No. 20-440

IN THE

Supreme Court of the United States

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

JOINT APPENDIX – VOLUME I

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PETITION FOR CERTIORARI FILED SEPT. 30, 2020
CERTIORARI GRANTED JAN. 8, 2021

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TABLE OF CONTENTS

NOTICE

The following documents have been omitted from the printing of this Joint Appendix. They may be found in the Appendix to the Petition for a Writ of Certiorari at the following pages:

U.S. DISTRICT COURT
DISTRICT OF DELAWARE (WILMINGTON)

———

Civil Docket For Case #: 1:15-cv-01031-JFB-SRF

———

HOLOGIC, INC. ET AL

v.

MINERVA SURGICAL, INC.

———

RELEVANT DOCKET ENTRIES

DATE	NO.	DOCKET TEXT
11/06/2015	1	COMPLAINT filed with Jury Demand against Minerva Surgical, Inc. - Magistrate Consent Notice to Pltf. (Filing fee $ 400, receipt number 1823358.) - filed by Hologic, Inc., Cytyc Surgical Products, LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(cna) (Additional attachment(s) added on 11/10/2015: # 4 Exhibit D) (sar). (Entered: 11/06/2015)
		* * *
02/05/2016	70	SECOND AMENDED COMPLAINT against Minerva Surgical, Inc.- filed by Hologic, Inc., Cytyc Surgical Products, LLC. (Attachments: # 1 part 2, # 2 part 3, # 3 part 4)(fms) (Entered: 02/05/2016)
		* * *

DATE	NO.	DOCKET TEXT
03/11/2016	85	REDACTED VERSION of 83 Answer to Amended Complaint,, Counterclaim, by Minerva Surgical, Inc.. (Schladweiler, Benjamin) (Entered: 03/11/2016)
		* * *
06/02/2016	127	MEMORANDUM ORDER denying 9 MOTION for Preliminary Injunction filed by Cytyc Surgical Products, LLC, Hologic, Inc. Signed by Judge Sue L. Robinson on 6/2/2016. (nmfn) (Entered: 06/02/2016)
		* * *
04/24/2017	227	MEMORANDUM ORDER re: claim construction. Signed by Judge Sue L. Robinson on 4/24/2017. (nmfn) (Entered: 04/24/2017)
		* * *
01/05/2018	277	MOTION for Partial Summary Judgment - filed by Minerva Surgical, Inc.. (Attachments: # 1 Text of Proposed Order)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	278	[SEALED] OPENING BRIEF in Support re 277 MOTION for Partial Summary Judgment filed by Minerva Surgical, Inc..Answering Brief/Response due date per Local Rules is 1/19/2018. (Attachments: # 1 Appendix) (Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
		* * *

DATE	NO.	DOCKET TEXT
01/05/2018	281	[SEALED] DECLARATION Volume I of V of Olivia M. Kim re 277 MOTION for Partial Summary Judgment, 279 MOTION to Preclude, 275 MOTION to Dismiss by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibits 3-5, # 4 Exhibits 6-8, # 5 Exhibits 9-14, # 6 Exhibits 15-34, # 7 Exhibits 35-40, # 8 Exhibits 41-43)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	282	[SEALED] DECLARATION Volume II of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 46-54)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	283	[SEALED] Exhibit Volume III of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 57-60, # 2 Exhibit 61, # 3 Exhibits 62-73, # 4 Exhibits 74-88)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	284	[SEALED] EXHIBIT Volume IV of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 100, # 2 Exhibit 101 - Parts 1-10, # 3 Exhibits 101 - Part 11 and Exhibit 112, # 4 Exhibits 113-120, # 5 Exhibits 121-126, # 6 Exhibits 127-137)(Schladweiler, Benjamin) Modified

DATE	NO.	DOCKET TEXT
		on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	285	[SEALED] EXHIBIT Volume V of V re 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 142, # 2 Exhibit 143 - Parts 1-5, # 3 Exhibits 144-145, # 4 Exhibits 146-147, # 5 Exhibits 148-150, # 6 Exhibits 151-153, # 7 Exhibit 154, # 8 Exhibit 155, # 9 Exhibits 156-161)(Schladweiler, Benjamin) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	286	NOTICE of filing the following Non-Paper material(s) in multi media format: CD containing Exhibits 17, 18, 20, 21, 23, 25, 27, 29, 31, 32, 33, 156, 157, and 158 to the Declaration of Olivia M. Kim in Support of Defendant Minerva's Motion to Dismiss, Motion for Partial Summary Judgment and Daubert Motion. Original Non-paper material(s) to be filed with the Clerk's Office. Notice filed by Benjamin J. Schladweiler on behalf of Minerva Surgical, Inc. (Schladweiler, Benjamin) (Entered: 01/05/2018)
01/05/2018	287	MOTION for Summary Judgment of No Invalidity - filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Text of Proposed Order)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)

DATE	NO.	DOCKET TEXT
01/05/2018	288	MOTION for Summary Judgment of Infringement - filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Text of Proposed Order)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	289	MOTION for Summary Judgment of Assignor Estoppel - filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Text of Proposed Order)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
		* * *
01/05/2018	291	[SEALED] OPENING BRIEF in Support re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment filed by Cytyc Surgical Products, LLC, Hologic, Inc..Answering Brief/Response due date per Local Rules is 1/19/2018. (Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	292	[SEALED] DECLARATION of Marc A. Cohn (Volume 1 of 2) re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 1 - 20, # 2 Exhibit 21 -

DATE	NO.	DOCKET TEXT
		45)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	293	[SEALED] DECLARATION (Volume 2 of 2) re 290 MOTION to Preclude, 287 MOTION for Summary Judgment, 289 MOTION for Summary Judgment, 288 MOTION for Summary Judgment by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 46 - 61, # 2 Exhibit 62 - 65, # 3 Exhibit 66 - 73, # 4 Exhibit 74 - 90, # 5 Exhibit 91 - 122)(Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	294	[SEALED] DECLARATION of Karl R. Leinsing, MSME, PE re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 1/8/2018 (lih). (Entered: 01/05/2018)
01/05/2018	295	NOTICE of of Filing of Multimedia Format by Cytyc Surgical Products, LLC, Hologic, Inc. re 293 Declaration,, (Pascale, Karen) (Entered: 01/05/2018)
01/08/2018	296	MULTI MEDIA DOCUMENT filed by Cytyc Surgical Products, LLC, Hologic, Inc. in the form of a CD Rom. (Media on file in Clerk's Office). (crb) (Entered: 01/08/2018)

DATE	NO.	DOCKET TEXT
01/09/2018	297	MULTI MEDIA DOCUMENT filed by Minerva Surgical, Inc. in the form of a CD ROM (Exhibits 17, 18, 20, 21, 23, 25, 27, 29, 31, 32, 33, 156, 157, 158). (Media on file in Clerk's Office). (crb) (Entered: 01/09/2018)
		* * *
01/16/2018	300	REDACTED VERSION of 278 Opening Brief in Support, by Minerva Surgical, Inc.. (Attachments: # 1 Appendix)(Schladweiler, Benjamin) (Entered: 01/16/2018)
		* * *
01/16/2018	302	REDACTED VERSION of 281 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibits 3-5, # 4 Exhibits 6-8, # 5 Exhibits 9-14, # 6 Exhibits 15-34, # 7 Exhibits 35-40, # 8 Exhibits 41-43)(Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	303	REDACTED VERSION of 282 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 46-54) (Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	305	REDACTED VERSION of 284 Exhibit to a Document by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 100, # 2 Exhibit 101 - Parts 1-10, # 3 Exhibits 101 - Part 11 and Exhibit 112, # 4 Exhibits 113-120, # 5

DATE	NO.	DOCKET TEXT
		Exhibits 121-126, # 6 Exhibits 127-137)(Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	306	REDACTED VERSION of 291 Opening Brief in Support by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	307	REDACTED VERSION of 292 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit s 1 through 45)(Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	308	REDACTED VERSION of 293 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit s 46 through 122)(Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	309	REDACTED VERSION of 294 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
01/16/2018	310	REDACTED VERSION of 285 Exhibit to a Document by Minerva Surgical, Inc.. (Attachments: # 1 Exhibit 142, # 2 Exhibit 143 - Parts 1-5, # 3 Exhibits 144-145, # 4 Exhibits 146-147, # 5 Exhibits 148-150, # 6 Exhibits 151-153, # 7 Exhibit 154, # 8 Exhibit 155, # 9 Exhibits 156-161)(Schladweiler,

DATE	NO.	DOCKET TEXT
		Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/16/2018)
		* * *
01/17/2018	311	REDACTED VERSION of 283 Exhibit to a Document by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 57-60, # 2 Exhibit 61, # 3 Exhibits 62-73, # 4 Exhibits 74-88)(Schladweiler, Benjamin) Modified on 1/17/2018 (lih). (Entered: 01/17/2018)
		* * *
02/14/2018	320	[SEALED] ANSWERING BRIEF in Opposition re 290 MOTION to Preclude, 287 MOTION for Summary Judgment, 289 MOTION for Summary Judgment, 288 MOTION for Summary Judgment filed by Minerva Surgical, Inc..Reply Brief due date per Local Rules is 2/21/2018. (Attachments: # 1 Supplemental Appendix A, # 2 Exhibit 1, # 3 Exhibit 2)(Schladweiler, Benjamin) Modified on 2/16/2018 (lih). (Main Document 320 replaced on 4/16/2018) (lih). (Entered: 02/14/2018)
02/14/2018	321	[SEALED] DECLARATION of Olivia M. Kim re 320 Answering Brief in Opposition by Minerva Surgical, Inc.. (Attachments: # 1 Vol. I of II (Exs. 162-197), # 2 Vol. II of II (Exs. 198-204))(Schladweiler, Benjamin) Modified on 2/16/2018 (lih). (Entered: 02/14/2018)

DATE	NO.	DOCKET TEXT
02/14/2018	322	NOTICE of filing the following Non-Paper material(s) in multi media format: (CD containing Exhibits 181, 182, 183, and 184 to Declaration of Olivia M. Kim in Support of Defendant Minerva's Opposition to Plaintiffs' Motions for Summary Judgment of Infringement, Assignor Estoppel, and No Invalidity and Motion to Exclude Expert Testimony). Original Non-paper material(s) to be filed with the Clerk's Office. Notice filed by Benjamin J. Schladweiler on behalf of Minerva Surgical, Inc. (Schladweiler, Benjamin) (Entered: 02/14/2018)
		* * *
02/14/2018	324	[SEALED] ANSWERING BRIEF in Opposition re 277 MOTION for Partial Summary Judgment, 279 MOTION to Preclude filed by Cytyc Surgical Products, LLC, Hologic, Inc..Reply Brief due date per Local Rules is 2/21/2018. (Pascale, Karen) Modified on 2/16/2018 (lih). (Entered: 02/14/2018)
02/14/2018	325	[SEALED] DECLARATION of Marc A. Cohn re 324 Answering Brief in Opposition,, 323 Answering Brief in Opposition by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 123-150, # 2 Exhibit 151 - 160, # 3 Exhibit 161 -

DATE	NO.	DOCKET TEXT
		170, # 4 Exhibit 171 - 180, # 5 Exhibit 181 - 190, # 6 Exhibit 191 - 202)(Pascale, Karen) Modified on 2/16/2018 (lih). (Entered: 02/14/2018)
02/14/2018	326	MULTI MEDIA DOCUMENT filed by Minerva Surgical, Inc. in the form of a CD Rom. Filing related to 322 Notice of Filing Multi Media Materials. (Media on file in Clerk's Office). (lih) (Entered: 02/16/2018)
		* * *
02/21/2018	329	REDACTED VERSION of 324 Answering Brief in Opposition by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 2/22/2018 (lih). (Entered: 02/21/2018)
02/21/2018	330	REDACTED VERSION of 325 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 123 - 202)(Pascale, Karen) Modified on 2/22/2018 (lih). (Entered: 02/21/2018)
02/21/2018	331	REDACTED VERSION of 320 Answering Brief in Opposition, by Minerva Surgical, Inc.. (Attachments: # 1 Supplemental Appendix A, # 2 Exhibit 1, # 3 Exhibit 2)(Schladweiler, Benjamin) (Entered: 02/21/2018)
02/21/2018	332	REDACTED VERSION of 321 Declaration by Minerva Surgical, Inc.. (Attachments: # 1 Vol. I of II (Exs. 162-197), # 2 Vol. II of II (Exs. 198-

DATE	NO.	DOCKET TEXT
		204))(Schladweiler, Benjamin) Modified on 2/22/2018 (lih). (Entered: 02/21/2018)
		* * *
03/28/2018	341	[SEALED] REPLY BRIEF re 277 MOTION for Partial Summary Judgment filed by Minerva Surgical, Inc.. (Attachments: # 1 Second Supplemental Appendix A) (Schladweiler, Benjamin) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)
		* * *
03/28/2018	343	[SEALED] DECLARATION of Olivia M. Kim re 342 Reply Brief, 340 Reply Brief, 341 Reply Brief by Minerva Surgical, Inc.. (Attachments: # 1 Exhibits 205-209)(Schladweiler, Benjamin) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)
03/28/2018	344	[SEALED] REPLY BRIEF re 290 MOTION to Preclude , 289 MOTION for Summary Judgment , 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment filed by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)
03/28/2018	345	[SEALED] DECLARATION of Marc A. Cohn re 344 Reply Brief, by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 203 - 210)(Pascale, Karen) Modified on 3/29/2018 (lih). (Entered: 03/28/2018)

DATE	NO.	DOCKET TEXT
		* * *
04/04/2018	351	REDACTED VERSION of 344 Reply Brief, by Cytyc Surgical Products, LLC, Hologic, Inc.. (Pascale, Karen) (Entered: 04/04/2018)
04/04/2018	352	REDACTED VERSION of 345 Declaration by Cytyc Surgical Products, LLC, Hologic, Inc.. (Attachments: # 1 Exhibit 203 - 210)(Pascale, Karen) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
		* * *
04/04/2018	354	REQUEST for Oral Argument by Minerva Surgical, Inc. re 277 MOTION for Partial Summary Judgment, 279 MOTION to Preclude, 275 MOTION to Dismiss . (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
04/04/2018	355	REDACTED VERSION of 340 Reply Brief by Minerva Surgical, Inc.. (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
04/04/2018	356	REDACTED VERSION of 341 Reply Brief by Minerva Surgical, Inc.. (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
		* * *
04/04/2018	358	REDACTED VERSION of 343 Declaration by Minerva Surgical, Inc.. (Schladweiler, Benjamin) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)

DATE	NO.	DOCKET TEXT
04/04/2018	359	REQUEST for Oral Argument by Cytyc Surgical Products, LLC, Hologic, Inc. re 290 MOTION to Preclude, 289 MOTION for Summary Judgment, 287 MOTION for Summary Judgment, 288 MOTION for Summary Judgment. (Pascale, Karen) Modified on 4/5/2018 (lih). (Entered: 04/04/2018)
		* * *
06/28/2018	407	MEMORANDUM OPINION Signed by Judge Joseph F. Bataillon on 6/28/2018. (nmf) (Entered: 06/28/2018)
06/28/2018	408	ORDER denying 275 Motion to Dismiss for Lack of Subject Jurisdiction ; denying 277 Motion for Partial Summary Judgment; denying 279 Motion to Preclude; granting 287 Motion for Summary Judgment ; granting 288 Motion for Summary Judgment ; granting 289 Motion for Summary Judgment ; denying 290 Motion to Preclude; denying 317 Motion to Strike ; denying 346 Motion to Strike ; denying 374 Motion to Bifurcate. Signed by Judge Joseph F. Bataillon on 6/28/2018. (nmf) (Entered: 06/28/2018)
		* * *
07/16/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/16/2018. (Court Reporter V. Gunning.) (DAY 1) (nmf) (Entered: 07/17/2018)

DATE	NO.	DOCKET TEXT
07/17/2018	485	Initial Jury Instructions read in Open Court 7/17/2018. (nmf) (Entered: 07/17/2018)
07/17/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/17/2018. (Court Reporter V. Gunning.) (DAY 2) (nmf) (Entered: 07/17/2018)
		* * *
07/18/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/18/2018. (Court Reporter V. Gunning.)(DAY 3) (nmf) (Entered: 07/18/2018)
		* * *
07/19/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/19/2018. (Court Reporter V. Gunning.)(DAY 4) (nmf) (Entered: 07/19/2018)
		* * *
07/20/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/20/2018. (Court Reporter V. Gunning.)(DAY 5) (nmf) (Entered: 07/20/2018)
		* * *
07/23/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/23/2018. (Court Reporter V. Gunning.)(DAY 6) (nmf) (Entered: 07/23/2018)

DATE	NO.	DOCKET TEXT
		* * *
07/24/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/24/2018. (Court Reporter V. Gunning.)(DAY 7) (nmf) (Entered: 07/24/2018)
07/25/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/25/2018. (Court Reporter V. Gunning.)(DAY 8) (nmf) (Entered: 07/25/2018)
		* * *
07/26/2018		Minute Entry for proceedings held before Judge Joseph F. Bataillon - Jury Trial held on 7/26/2018. Closing Arguments, Final Instructions, and Deliberations (Court Reporter Valerie Gunning.)(DAY 9) (crb) (Entered: 07/26/2018)
		* * *
07/26/2018	496	Revised Initial Jury Instructions read in Open Court 7/26/2018. (nmf) (Entered: 07/27/2018)
07/26/2018	497	Closing Jury Instructions read in Open Court 7/26/2018. (nmf) (Entered: 07/27/2018)
07/27/2018		Minute Entry for proceedings held before Magistrate Judge Sherry R. Fallon - Jury Trial completed on 7/27/2018. (Court Reporter V. Gunning.)(DAY 10) (Deliberations and Verdict) (nmf) (Entered: 07/27/2018)

DATE	NO.	DOCKET TEXT
07/27/2018	498	[SEALED] JURY VERDICT. (nmf) (Entered: 07/27/2018)
07/27/2018	499	REDACTED VERSION of 498 Jury Verdict. (nmf) (Entered: 07/27/2018)

* * *

08/08/2018	507	Official Transcript of jury trial held on July 16, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	508	Official Transcript of jury trial held on July 17, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018.

DATE	NO.	DOCKET TEXT
		Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	509	Official Transcript of jury trial held on July 19, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	510	Official Transcript of jury trial held on July 20, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	511	Official Transcript of jury trial held on July 23, 2018 before Judge Bataillon.

DATE	NO.	DOCKET TEXT
		Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	512	Official Transcript of jury trial held on July 24, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	513	Official Transcript of jury trial held on July 18, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or

DATE	NO.	DOCKET TEXT
		purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	514	Official Transcript of jury trial held on July 25, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	515	Official Transcript of jury trial held on July 26, 2018 before Judge Bataillon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained

DATE	NO.	DOCKET TEXT
		through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
08/08/2018	516	Official Transcript of jury trial held on July 27, 2018 before Judge Fallon. Court Reporter/Transcriber Valerie Gunning,Telephone number (302) 573-6194. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/ Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 8/29/2018. Redacted Transcript Deadline set for 9/10/2018. Release of Transcript Restriction set for 11/6/2018. (vjg) (Entered: 08/08/2018)
		* * *
08/13/2018	520	JUDGMENT FOLLOWING JURY VERDICT: IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered on the July 27, 2018 verdict as set forth in the attached verdict form and on the June 28, 2018 Order (D.I. 408). IT IS FURTHER NOTED that this Judgment Following Jury Verdict is subject to revision pursuant to any rulings on post–trial motions. Signed by Judge Joseph F. Bataillon on

DATE	NO.	DOCKET TEXT
		8/13/2018. (nmf) (Entered: 08/13/2018)
		* * *
05/02/2019	616	MEMORANDUM AND ORDER: Defendant's renewed motion for judgment as a matter of law (D.I. 521) is DENIED. Defendant's motion for a new trial (D.I. 523) is DENIED. Defendant's motion for an injunction under the Deceptive Trade Practices Act (D.I. 525) is DENIED. Plaintiffs' motion for attorney fees (D.I. 528) is DENIED. Plaintiffs' motion for enhanced damages (D.I. 530) is DENIED. Plaintiffs' motion (D.I. 532) for a permanent injunction and accounting is DENIED as moot. Plaintiffs' motion for an accounting, supplemental damages, ongoing royalties, prejudgment interest, and post–judgment interest (D.I. 534) is GRANTED in part and DENIED in part as set forth in this order. The parties shall each submit a proposed final judgment to the Court within three weeks of the date of this order (*see Order for details). Signed by Judge Joseph F. Bataillon on 5/1/2019. (ceg) (Entered: 05/02/2019)
		* * *
06/03/2019	621	FINAL JUDGMENT: Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC,

DATE	NO.	DOCKET TEXT
		and against defendant/counterclaimant Minerva, Inc., on plaintiffs/counterclaim defendants claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $4,787,668.23. Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc., on plaintiffs/counterclaim defendants claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $1,629,304.08. Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc. on defendant/ counterclaimant Minervas counter-claims. Defendant/counterclaimant Minerva's counterclaims are hereby dismissed (*see Order for further details)(*CASE CLOSED). Signed by Judge Joseph F. Bataillon on 5/31/2019. (ceg) (Entered: 06/03/2019)
		* * *
06/28/2019	625	NOTICE OF CROSS APPEAL to the Federal Circuit of 621 Judgment,,,, 227 Memorandum and Order, 407 Memorandum Opinion, 520 Judgment, 408 Order on Motion to Dismiss/Lack of Subject Jurisdiction,, Order on Motion for Partial Summary Judgment,, Order on Motion to Preclude,, Order

DATE	NO.	DOCKET TEXT
		on Motion for Summary Judgment,,,,,,,, Order on Motion to Strike,,,, Order on Motion to Bifurcate, 616 Memorandum and Order,,, . Cross Appeal filed by Minerva Surgical, Inc.. (Schladweiler, Benjamin) (Entered: 06/28/2019)
07/02/2019	626	NOTICE of Docketing Record on Appeal from USCA for the Federal Circuit re 625 Notice of Cross Appeal filed by Minerva Surgical, Inc. USCA Case Number 19-2081. (nmg) (Entered: 07/02/2019)
		* * *
07/22/2020	634	ORDER of USCA. Decision of USCA: The petitions for panel rehearing are denied. The petitions for rehearing en banc are denied. (kmd) (Entered: 07/29/2020)
07/29/2020	635	MANDATE of USCA as to 625 Notice of Cross Appeal, filed by Minerva Surgical, Inc., 622 Notice of Appeal (Federal Circuit), filed by Cytyc Surgical Products, LLC, Hologic, Inc. USCA Decision: Affirmed-in-Part, Vacated-in-Part, and Remanded. (Attachments: # 1 Opinion, # 2 Judgment)(kmd) (Entered: 07/29/2020)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 19-2081

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs - Appellants

v.

MINERVA SURGICAL, INC.,
Defendant - Cross-Appellant

DOCKET ENTRIES

DATE	NO.	DOCKET TEXT
06/21/2019	1	Appeal docketed. Received: 06/18/2019. [615979] Entry of Appearance due 07/05/2019. Certificate of Interest is due on 07/05/2019. Docketing Statement due 07/05/2019. Appellant's brief is due 08/20/2019. [TAM] [Entered: 06/21/2019 09:48 AM]
06/21/2019	2	Entry of appearance for Matthew M. Wolf as principal counsel for Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 06/21/2019 by email. [616034] [19-2054] [Matthew Wolf] [Entered: 06/21/2019 01:00 PM]
06/21/2019	3	Certificate of Interest for Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 06/21/2019 by email. [616035] [19-2054] [Matthew Wolf] [Entered: 06/21/2019 01:03 PM]

DATE	NO.	DOCKET TEXT
06/21/2019	4	MOTION of Appellants Cytyc Surgical Products, LLC and Hologic, Inc. to expedite briefing schedule [Consent: opposed]. Service: 06/21/2019 by email. [616037] [19-2054] [Matthew Wolf] [Entered: 06/21/2019 01:08 PM]
06/21/2019	5	Entry of appearance for Jennifer A. Sklenar as of counsel for Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 06/21/2019 by email. [616038] [19-2054] [Jennifer Sklenar] [Entered: 06/21/2019 01:10 PM]
06/21/2019	6	Entry of appearance for Marc A. Cohn as of counsel for Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 06/21/2019 by email. [616039] [19-2054] [Marc Cohn] [Entered: 06/21/2019 01:13 PM]
06/21/2019	7	ORDER filed. Any opposition to the motion [4] is due no later than June 28, 2019. Any reply in support of the motion is due no later than July 1, 2019. Service: 06/21/2019 by clerk. [616093] [LMS] [Entered: 06/21/2019 03:08 PM]
06/28/2019	8	Entry of appearance for Robert N. Hochman as principal counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617823] [19-2054] [Robert Hochman] [Entered: 06/28/2019 02:36 PM]

DATE	NO.	DOCKET TEXT
06/28/2019	9	Entry of appearance for Caroline A. Wong as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617824] [19-2054] [Caroline Wong] [Entered: 06/28/2019 02:39 PM]
06/28/2019	10	Entry of appearance for Jillian Sheridan Stonecipher as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617825] [19-2054] [Jillian Stonecipher] [Entered: 06/28/2019 02:41 PM]
06/28/2019	11	Entry of appearance for Vera M. Elson as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617852] [19-2054] [Vera Elson] [Entered: 06/28/2019 03:23 PM]
06/28/2019	12	Entry of appearance for Edward G. Poplawski as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617859] [19-2054] [Edward Poplawski] [Entered: 06/28/2019 03:36 PM]
06/28/2019	13	Entry of appearance for Olivia M. Kim as of counsel for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617861] [19-2054] [Olivia Kim] [Entered: 06/28/2019 03:41 PM]
06/28/2019	14	Certificate of Interest for Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617865] [19-2054] [Robert Hochman] [Entered:

DATE	NO.	DOCKET TEXT
		06/28/2019 03:47 PM]
06/28/2019	15	Docketing Statement for the Appellee Minerva Surgical, Inc.. Service: 06/28/2019 by email. [617868] [19-2054] [Robert Hochman] [Entered: 06/28/2019 03:48 PM]
06/28/2019	1	RESPONSE of Appellee Minerva Surgical, Inc. to the motion [4] filed by Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 06/28/2019 by email. [617872] [19-2054] [Robert Hochman] [Entered: 06/28/2019 03:52 PM]
07/01/2019	17	REPLY of Appellants Hologic, Inc. and Cytyc Surgical Products, LLC to response [16]. Service: 07/01/2019 by email. [618214] [19-2054] [Matthew Wolf] [Entered: 07/01/2019 02:07 PM]
07/02/2019	18	Note to file: The following cases are associated:19-2054 (Lead) with 19-2081 (Cross-Appeal). FURTHER ENTRIES WILL BE ADDED TO THE LEAD APPEAL ONLY. [618504] [19-2054, 19-2081] [TAM] [Entered: 07/02/2019 10:58 AM]
07/02/2019	19	Official caption revised to reflect Cross-Appeal. The official caption is reflected on the electronic docket under the listing of the parties and counsel. Service as of thAs date by the Clerk of Court. [618509] [TAM] [Entered: 07/02/2019 11:01 AM]

DATE	NO.	DOCKET TEXT
07/03/2019	20	Docketing Statement for the Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Service: 07/03/2019 by email. [618906] [19-2054] [Matthew Wolf] [Entered: 07/03/2019 12:45 PM]
07/03/2019	21	ORDER filed. The motion [4] is granted to the extent that Hologic's opening brief is due no later than July 15, 2019; Minerva's principal-and-response brief is due no later than August 26, 2019; Hologic's response-and-reply brief is due no later than September 9, 2019; Minerva's reply brief is due no later than September 23, 2019; the joint appendix is due no later than September 30, 2019; and the case will be placed on the December 2019 oral argument calendar. Service: 07/03/2019 by clerk. [618968] [LMS] [Entered: 07/03/2019 02:35 PM]
07/15/2019	22	FILED from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Title: CONFIDENTIAL OPENING BRIEF. Service: 07/15/2019 by email. [621120] [19-2054] This document is non-compliant. See Doc No.[24] [Matthew Wolf] [Entered: 07/15/2019 05:31 PM]
07/15/2019	23	FILED from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. Title: OPENING BRIEF. Service:

DATE	NO.	DOCKET TEXT
		07/15/2019 by email. [621121] [19-2054] This document is non-compliant. See Doc No.[24] [Matthew Wolf] [Entered: 07/15/2019 05:34 PM]
07/25/2019	24	NOTICE OF NON-COMPLIANCE: The submissions of Appellants Cytyc Surgical Products, LLC and Hologic, Inc., Confidential and Non-Confidential Opening Briefs [22], [23], are not in compliance with the rules of this court (see attached). Compliant documents due on 08/01/2019. Service as of this date by the Clerk of Court. [623538] [TAM] [Entered: 07/25/2019 02:44 PM]
07/31/2019	25	MODIFIED ENTRY: CORRECTED OPENING BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 71. Service: 07/31/2019 by email. [625030] --[Edited 08/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 07/31/2019 04:53 PM]
07/31/2019	26	MODIFIED ENTRY: CORRECTED CONFIDENTIAL OPENING BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 71. Service: 07/31/2019 by email. [625031]--[Edited 08/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 07/31/2019 04:55 PM]

DATE	NO.	DOCKET TEXT
08/26/2019	27	MODIFIED ENTRY: RESPONSE BRIEF FILED for Cross-Appellant Minerva Surgical, Inc. Number of Pages: 95. Service: 08/26/2019 by email. Unless ordered otherwise, any responsive deadline runs from the date of service of this brief. See Fed. Cir. R. 31. [631081] --[Edited 09/04/2019 by TAM - compliance review complete] [Robert Hochman] [Entered: 08/26/2019 04:01 PM]
09/09/2019	28	FILED from Appellants Cytyc Surgical Products, LLC, Hologic, Inc. and Cross-Appellant Minerva Surgical, Inc.. Title: CONFIDENTIAL REPLY BRIEF. Service: 09/09/2019 by email. [634161] [19-2054] This document is non-compliant. See Doc No.[30] [Matthew Wolf] [Entered: 09/09/2019 07:01 PM]
09/09/2019	29	FILED from Appellants Cytyc Surgical Products, LLC, Hologic, Inc. and Cross-Appellant Minerva Surgical, Inc.. Title: REPLY BRIEF. Service: 09/09/2019 by email. [634163] [19-2054] This document is non-compliant. See Doc No.[30] [Matthew Wolf] [Entered: 09/09/2019 07:04 PM]
09/20/2019	30	NOTICE OF NON-COMPLIANCE: The submissions of Appellants Cytyc Surgical Products, LLC and Hologic, Inc., Confidential and Non-Confidential Reply Brief [28], [29], are

DATE	NO.	DOCKET TEXT
		not in compliance with the rules of this court (see attached). Compliant documents due on 09/27/2019. The deadline for any responsive filing runs from service of the original version. Service as of this date by the Clerk of Court. [636949] [TAM] [Entered: 09/20/2019 09:10 AM]
09/23/2019	31	MODIFIED ENTRY: CORRECTED REPLY BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 64. Service: 09/23/2019 by email. [637486] --[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/23/2019 03:04 PM]
09/23/2019	32	MODIFIED ENTRY: CORRECTED CONFIDENTIAL REPLY BRIEF FILED for Appellants Cytyc Surgical Products, LLC and Hologic, Inc. Number of Pages: 64. Service: 09/23/2019 by email. [637487]--[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/23/2019 03:07 PM]
09/23/2019	33	MODIFIED ENTRY: REPLY BRIEF FILED for Cross-Appellant Minerva Surgical, Inc. Number of Pages: 39. Service: 09/23/2019 by email. Unless ordered otherwise, any responsive deadline runs from the date of service of this brief. See Fed. Cir. R. 31.

DATE	NO.	DOCKET TEXT
		[637577] --[Edited 10/01/2019 by TAM - compliance review complete] [Robert Hochman] [Entered: 09/23/2019 04:44 PM]
09/30/2019	34	MODIFIED ENTRY: APPENDIX FILED for Cytyc Surgical Products, LLC, Hologic, Inc. and Minerva Surgical, Inc.. Number of Pages: 1091. Service: 09/30/2019 by email. [639243] --[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/30/2019 10:06 PM]
09/30/2019	35	MODIFIED ENTRY: CONFIDENTIAL APPENDIX FILED for Cytyc Surgical Products, LLC, Hologic, Inc. and Minerva Surgical, Inc.. Number of Pages: 1523. Service: 09/30/2019 by email. [639244]--[Edited 10/01/2019 by TAM - compliance review complete] [Matthew Wolf] [Entered: 09/30/2019 10:10 PM]
09/30/2019	36	Joint Statement of Compliance with Fed. Cir. R. 33 for Appellants Hologic, Inc., Cytyc Surgical Products, LLC and Cross-Appellant Minerva Surgical, Inc.. Service: 09/30/2019 by email. [639245] [19-2054] [Matthew Wolf] [Entered: 09/30/2019 10:13 PM]
09/30/2019	37	Certificate of Compliance with Fed. Cir. R. 11(d) (Trial Court) for Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service:

DATE	NO.	DOCKET TEXT
		09/30/2019 by email. [639246] [19-2054] [Matthew Wolf] [Entered: 09/30/2019 10:14 PM]
09/30/2019	38	Certificate of Compliance with Fed. Cir. R. 11(d) (Trial Court) for Cross-Appellant Minerva Surgical, Inc.. Service: 09/30/2019 by email. [639247] [19-2054] [Robert Hochman] [Entered: 09/30/2019 10:14 PM]
09/30/2019	39	Notice from Appellants Hologic, Inc. and Cytyc Surgical Products, LLC Notice of Intent to File Supplemental Appendix of Video Recordings on CD-ROM. Service: 09/30/2019 by email. [639248] [19-2054] [Matthew Wolf] [Entered: 09/30/2019 10:20 PM]
09/30/2019	40	Supplementary Video Media Appendix received on CD-ROM from Cytyc Surgical Products, LLC and Hologic, Inc. Number of copies: 4. [639425] [JCP] [Entered: 10/01/2019 03:26 PM]
10/01/2019	41	Outstanding paper copies of all briefs and appendices must be submitted within five business days from the date of issuance of this notice. See Fed. Cir. R. 25(c)(1). [639455] [TAM] [Entered: 10/01/2019 04:08 PM]
10/01/2019	42	Notice to Advise of Scheduling Conflicts. Arguing counsel must advise of, and show good cause for, any scheduling conflicts during the upcoming court session months listed

DATE	NO.	DOCKET TEXT
		in the attached notice. The Response to Notice to Advise of Scheduling Conflicts can be found here. The Oral Argument Guide can be found here. [639462] [TAM] [Entered: 10/01/2019 04:14 PM]
10/04/2019	43	6 paper copies of the Corrected Confidential Opening Brief [26] received from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. [640315] [CJF] [Entered: 10/04/2019 12:54 PM]
10/04/2019	44	6 paper copies of the Corrected Confidential Reply Brief [32] received from Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. [640318] [CJF] [Entered: 10/04/2019 12:55 PM]
10/04/2019	45	6 paper copies of the Confidential Appendix Brief (Vol. I - IV) [35] received from Appellants Cytyc Surgical Products, LLC, Hologic, Inc. and Cross-Appellant Minerva Surgical, Inc.. [640319] [CJF] [Entered: 10/04/2019 12:55 PM]
10/04/2019	46	Notice from Appellants Hologic, Inc. and Cytyc Surgical Products, LLC regarding conflicts with oral argument. Service: 10/04/2019 by email. [640326] [19-2054] [Matthew Wolf] [Entered: 10/04/2019 01:06 PM]
10/04/2019	47	The following conflict dates submitted by Attorney Matthew Wolf for

DATE	NO.	DOCKET TEXT
		Appellants Hologic, Inc. and Cytyc Surgical Products, LLC have been accepted by the court: 01/08/2020, 01/09/2020, 01/10/2020, 02/03/2020, 02/04/2020, 02/05/2020, 02/06/2020, 02/07/2020, 04/09/2020, 04/10/2020. [640340] [JAB] [Entered: 10/04/2019 01:28 PM]
10/08/2019	48	Notice from Cross-Appellant Minerva Surgical, Inc. regarding conflicts with oral argument. Service: 10/08/2019 by email. [641158] [19-2054] [Robert Hochman] [Entered: 10/08/2019 04:41 PM]
10/08/2019	49	6 paper copies of the Reply Brief [33] received from Cross-Appellant Minerva Surgical, Inc.. [641185] [CJF] [Entered: 10/09/2019 07:36 AM]
10/08/2019	50	6 paper copies of the Opening Response Brief [27] received from Cross-Appellant Minerva Surgical, Inc.. [641186] [CJF] [Entered: 10/09/2019 07:37 AM]
10/09/2019	51	The following conflict dates submitted by Attorney Robert N. Hochman for Cross-Appellant Minerva Surgical, Inc. have been accepted by the court: 12/02/2019, 12/03/2019. [641206] [JAB] [Entered: 10/09/2019 08:58 AM]
10/21/2019	52	NOTICE OF ORAL ARGUMENT. Panel: 1912I. Case scheduled December 4, 2019 10:00 a.m. at the United States Court of Appeals for the

DATE	NO.	DOCKET TEXT
		Federal Circuit (Howard T. Markey National Courts Building, 717 Madison Place, NW Washington, DC 20439), Courtroom 203. Response to Notice of Oral Argument due: 11/15/2019. Please review the attached Notice. The response to notice of oral argument form can be found here. The Oral Argument Guide can be found here. [643499] [JAB] [Entered: 10/21/2019 02:19 PM]
11/07/2019	53	Response to notice of oral argument from the Cross-Appellant Minerva Surgical, Inc.. [647742] [19-2054] [Robert Hochman] [Entered: 11/07/2019 01:09 PM]
11/15/2019	54	Response to notice of oral argument from the Appellants Cytyc Surgical Products, LLC and Hologic, Inc.. [649584] [19-2054] [Matthew Wolf] [Entered: 11/15/2019 10:05 AM]
12/04/2019	55	Submitted after ORAL ARGUMENT by Matthew Wolf for Hologic, Inc. and Cytyc Surgical Products, LLC and Robert N. Hochman for Minerva Surgical, Inc. Panel: Judge: Wallach , Judge: Clevenger , Judge: Stoll. [653886] [JCP] [Entered: 12/04/2019 10:25 AM]
04/22/2020	56	OPINION filed for the court by Wallach, Circuit Judge; Clevenger, Circuit Judge and Stoll, Circuit Judge. Precedential Opinion. [689037]

DATE	NO.	DOCKET TEXT
		[19-2054, 19-2081] [JAB] [Entered: 04/22/2020 10:03 AM]
04/22/2020	57	JUDGMENT. AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED. Terminated on the merits after oral argument. COSTS: No Costs. Mandate to issue in due course. For information regarding costs, petitions for rehearing, and petitions for writs of certiorari click here. [689039] [19-2054, 19-2081] [JAB] [Entered: 04/22/2020 10:04 AM]
05/22/2020	58	Petition for panel rehearing, for en banc rehearing filed by Cross-Appellant Minerva Surgical, Inc.. Service: 05/22/2020 by email. [696559] [19-2054] [Robert Hochman] [Entered: 05/22/2020 12:52 PM]
05/22/2020	59	Petition for en banc rehearing filed by Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 05/22/2020 by email. [696694] [19-2054] [Matthew Wolf] [Entered: 05/22/2020 05:17 PM]
05/27/2020	60	18 paper copies of the combined petition for panel rehearing and rehearing en banc [58] received from Minerva Surgical, Inc. [697254] [MJL] [Entered: 05/27/2020 03:07 PM]
06/04/2020	61	The court invites a response from Appellants Cytyc Surgical Products, LLC and Hologic, Inc. to the petition for panel rehearing, for en banc

DATE	NO.	DOCKET TEXT
		rehearing filed by Cross-Appellant in 19-2054; and invites a response from Cross-Appellant Minerva Surgical, Inc. to the petition for en banc rehearing filed by Appellants in 19-2054. The responses are due on or before 06/18/2020. [699240] [JAB] [Entered: 06/04/2020 01:22 PM]
06/05/2020	62	Entry of appearance for Mark A. Lemley as principal counsel for Amici Curiae 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review. Service: 06/05/2020 by email. [699573] [19-2054] [Mark Lemley] [Entered: 06/05/2020 01:13 PM]
06/05/2020	63	FILED from Amici Curiae 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review Title: AMICUS CURIAE BRIEF. Service: 06/05/2020 by email. [699576] [19-2054] This document is non-compliant. See Doc. No. [65]. [Mark Lemley] [Entered: 06/05/2020 01:18 PM]
06/05/2020	64	Certificate of Interest for Amici Curiae 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review. Service: 06/05/2020 by email. [699583] [19-2054] [Mark Lemley] [Entered: 06/05/2020 01:20 PM]

DATE	NO.	DOCKET TEXT
06/08/2020	65	NOTICE OF NON-COMPLIANCE: The submission of Movant 26 Intellectual Property Professors, Amicus Curiae Brief [63], is not in compliance with the rules of this court (see attached). Compliant document due on 06/15/2020. Service as of this date by the Clerk of Court. [699801] [JAB] [Entered: 06/08/2020 12:22 PM]
06/09/2020	66	MOTION of 26 Intellectual Property Professors in Support of Granting the Petition for En Banc Review for leave to file amicus brief in support of Neither party. The brief is in support of granting the Petition for En Banc Review. on petition [59], petition [58], petition [58] [Consent: unopposed]. Service: 06/09/2020 by email. [700194] [19-2054] [Mark Lemley] [Entered: 06/09/2020 05:48 PM]
06/10/2020	67	ORDER filed granting motion leave to file amicus brief on en banc or rehearing petition [66]. By: Merits Panel (Per Curiam). Service as of this date by the Clerk of Court. [700292] [JAB] [Entered: 06/10/2020 11:46 AM]
06/10/2020	68	CORRECTED AMICUS BRIEF FILED on Petition for 26 Intellectual Property Professors. Pages: 13. Service: 06/09/2020 by email. [700293] [JAB] [Entered: 06/10/2020 11:50 AM]
06/18/2020	69	RESPONSE of Cross-Appellant Minerva Surgical, Inc. to the petition

DATE	NO.	DOCKET TEXT
		[59] filed by Appellants Hologic, Inc. and Cytyc Surgical Products, LLC. Service: 06/18/2020 by email. [702319] [19-2054] [Robert Hochman] [Entered: 06/18/2020 06:47 PM]
06/18/2020	70	RESPONSE of Appellants Cytyc Surgical Products, LLC and Hologic, Inc. to the petition for panel rehearing [58] filed by Cross-Appellant Minerva Surgical, Inc., petition for en banc rehearing [58] filed by Cross-Appellant Minerva Surgical, Inc.. Service: 06/18/2020 by email. [702326] [19-2054] [Matthew Wolf] [Entered: 06/18/2020 09:15 PM]
06/23/2020	71	18 paper copies of the response [69] received from Minerva Surgical, Inc. [703102] [MJL] [Entered: 06/23/2020 02:18 PM]
07/22/2020	72	ORDER filed denying [59] petition for en banc rehearing filed by Hologic, Inc. and Cytyc Surgical Products, LLC, denying [58] petition for panel rehearing, for en banc rehearing filed by Minerva Surgical, Inc. By: En Banc (Per Curiam). Service as of this date by the Clerk of Court. [709185] [JAB] [Entered: 07/22/2020 11:15 AM]
07/29/2020	73	Mandate issued to the United States District Court for the District of Delaware. Service as of this date by the Clerk of Court. [710906] [19-2054,

DATE	NO.	DOCKET TEXT
		19-2081] [JAB] [Entered: 07/29/2020 10:01 AM]
10/08/2020	74	Petition for writ of certiorari filed on 09/30/2020, and placed on the docket 10/06/2020, in the U.S. Supreme Court. No.: 20-440, Minerva Surgical, Inc. v. Hologic, Inc., et al. [727549] [JAB] [Entered: 10/08/2020 08:29 AM]
11/13/2020	75	Petition for writ of certiorari filed on 11/05/2020, and placed on the docket 11/10/2020, in the U.S. Supreme Court. No.: 20-631, Hologic, Inc., et al. v. Minerva Surgical, Inc. [735330] [MJL] [Entered: 11/13/2020 10:54 AM]
01/11/2021	76	The petition for writ of certiorari, No. 20-631, filed on 11/05/2020, was Denied on 01/11/2021. [748430] [JAB] [Entered: 01/11/2021 02:50 PM]
01/11/2021	77	The petition for writ of certiorari, No. 20-440, filed on 09/30/2020, was Granted on 01/08/2021. [748441] [JAB] [Entered: 01/11/2021 03:01 PM]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No.: 1:15-cv-01031-SLR

HOLOGIC, INC., a Delaware corporation; and CYTYC SURGICAL PRODUCTS, LLC, a Delaware corporation,

Plaintiffs,

v.

MINERVA SURGICAL, INC., a Delaware corporation,

Defendant.

DECLARATION OF DR. EDWARD EVANTASH
IN SUPPORT OF HOLOGIC, INC.'S
MOTION FOR A PRELIMINARY INJUNCTION

FILED UNDER SEAL

I, Edward Evantash, state and declare as follows:

1. I am over the age of 21 and am competent to make this declaration. I am employed by Hologic, Inc. and I have worked at Hologic for over six years. My current title at Hologic is Vice President of Medical Affairs. I provide this declaration in support of Hologic's motion for a preliminary injunction. If called as a witness, I could and would testify competently to the information contained herein.

2. My practice and expertise is in Obstetrics and Gynecology, the medical field for which I did my medical residency and training in the early 1990s. Over the past 6 years, I have worked at Hologic, including as a Medical Director and Vice President of

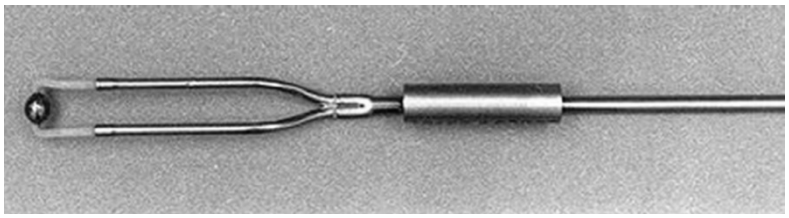
Medical Affairs. Prior to Hologic, I worked at Tufts University as a Director at the Center for Abnormal Uterine Bleeding. I worked at Tufts University for 15 years. Over the past two decades, a focus in my professional work has been clinical research and practice in addressing abnormal uterine bleeding in women, a medical condition known as menorrhagia.

3. Physicians have employed a number of techniques to address the problem of abnormal uterine bleeding in women. For example, many women have decided to undergo a hysterectomy, a surgery which removes a woman's uterus. In the 1990s, however, endometrial ablation gained in popularity as an alternative to hysterectomy. Endometrial ablation is a surgical procedure that destroys the endometrial lining of the uterus, but otherwise does not remove or destroy the remainder of the uterus.

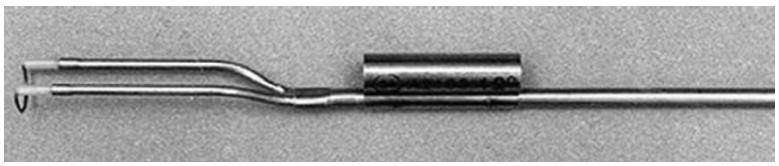
4. In the 1990s, physicians performed endometrial ablation using first generation techniques, including (1) the burning of endometrial tissue with an electrosurgical metal rollerball; and (2) endometrial resection with a metal wire loop electrode. Electricity was conducted from the metal instrument and applied to the endometrial tissue, which would be cauterized through heat and thus destroyed.

5. The rollerball technique used energy for heating the tissue to a temperature between 60 to 90ºC. The uterine lining is destroyed by contact with the heated ball that the physician must roll slowly over the surface of the endometrial lining, burning it away. The physician must be skilled to roll the small-sized, heated ball systematically across the various sections of the uterus to burn the endometrial lining throughout. A physician would perform the rollerball proce-

dure under direct visualization with a hysteroscope. Here is a photograph of a rollerball instrument:

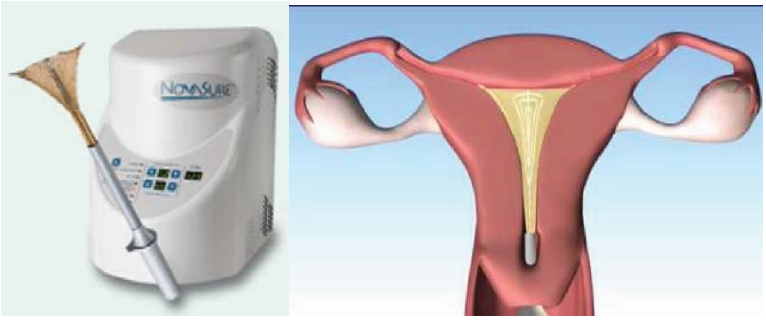


6. Another first generation method was endometrial resection with a metal wire loop. Using the metal wire loop, the physician would systematically strip off the lining of the uterus. The physician would resect or strip away the uterine lining with the wire loop under direct visualization of a hysteroscope. Similar to the rollerball, the physician must be skilled to manually strip away the uterine lining, bit by bit, using a small wire loop throughout the cavity of the uterus. Here is a photograph of an instrument using the wire loop:



7. With the introduction of the NovaSure endometrial ablation system (the "NovaSure system"), endometrial ablation came a long way from the first generation techniques that were employed in the 1990s to address abnormal uterine bleeding without hysterectomy. The NovaSure system became the leading system in a second generation of devices, known for global endometrial ablation. With global endometrial ablation, the NovaSure system treated all areas of the endometrial cavity simultaneously, with minimal hand manipulation. With the NovaSure system, the physician did not need move a small heated ball or a small wire loop manually in a systemic and tedious

procedure that would burn or strip away bit by bit the endometrial lining of the uterus. The rollerball and wire loop techniques presented serious risks to the patient because of the possibility of electrocuting nearby organs. By contrast, the NovaSure system employed an elongated device with an expandable applicator head that conformed to the shape of the uterus to treat the entire endometrial cavity simultaneously in two minutes or less. On the left is a photograph of an early NovaSure system using a mesh applicator head, and on the right, is an illustration of a NovaSure mesh application treating the entire cavity at once.



8. With first generation techniques, physicians needed to distend the uterus with a non-conducting fluid under pressure. This distention required careful control of the fluid pressure to avoid forcing the potentially toxic fluid into the bloodstream via the vessels in the uterine wall (known as intravasation) or into the abdominal cavity via the fallopian tubes. Using the NovaSure system eliminates the need for a non-conducting fluid inside the uterus, thus avoiding the risk of intravasation.

9. Further, the NovaSure system has provided a computerized and sensor-based integrity test to monitor for any perforations (i.e., holes) of the uterus before

administering treatment. Prior to the NovaSure system, a physician had to rely on a manual, visual inspection to identify any perforations in the uterus before the ablation treatment because these perforations could allow steam or hot fluids to escape the uterus and cause serious organ injury to the patient. Physicians would inspect for perforations visually using a tool called a hysteroscope which, when inserted transcervically, allowed a physician to view the inside of the uterus. But, the physician sometimes could not see small perforations with this procedure because the view from a hysteroscope could be limited and/or the uterus had irregularities. In short, spotting perforations with the prior techniques required a high-level of physician skill, and had to be performed in the controlled setting of an operating room.

10. In addition, the NovaSure uses feedback from the tissue itself to customize each ablation. This is because the total amount of energy delivered depends on the impedance (i.e., electrical resistance) of the tissue in contact with the applicator head. In other words, the energy delivery occurs where it is needed most, i.e., deeper tissues receive more energy, and this helps to control the amount of energy delivery during treatment.

11. During the ablation procedure, the energy delivery causes steam and hot moisture to develop inside the uterine cavity. To avoid this moisture from building up inside the cavity, NovaSure provides "moisture transport" functionality that removes the moisture from the cavity.

12. With the above technical advances, including the treatment of all areas of the endometrial cavity simultaneously, the NovaSure system revolutionized the procedure of endometrial ablation as a safer

alternative to first generation techniques for treating abnormal uterine bleeding. Further, as a practical matter, the NovaSure procedure could be performed in a physician's office in five minutes. The first generation techniques required the use of an operating room at a surgery center, where the surgeon would take about 30 to 50 minutes to burn or strip away the portions of the endometrial lining. Because the NovaSure procedure could be performed in a physician's office, such procedures could be less expensive, less intimidating, and substantially more convenient and comfortable for the patient.

13. The NovaSure system continues to provide a sensor-based, computerized integrity test of the uterus before any treatment can occur. The purpose of the integrity test is to assess whether any perforations (i.e., holes) of the uterus are present. Serious injury can occur if perforations are present in the uterus during treatment because hot steam or fluids generated during treatment can escape through the small perforations to damage nearby organs. The NovaSure system originally implemented its computerized integrity test because the clinical data made clear that endometrial ablation should not be performed if the uterus had any perforation, even a small one. Thus, perforation detection has been critically important. Therefore, if a perforation is present in the uterus, the NovaSure system will not start the treatment. NovaSure tests for perforations by sealing the uterus and supplying carbon dioxide gas into the uterus, and then measuring whether there is any flow of gas out of the uterus indicating the presence of a hole. This sensor-based, computerized monitoring for perforations is substantially more accurate than the prior technique of a physician conducting a manual, visual inspection with a hysteroscope. Hologic maintains a

post-market quality assurance tracking of all reportable complications through its representatives and by direct communication with health care providers. Based on this information, Hologic estimates the rate of bowel injury with NovaSure endometrial ablation is less than 1 in 10,000 procedures. These safety rates can be attributed to the NovaSure system pioneering the implementation of its uterine integrity test before endometrial ablation treatment can proceed.

14. Because of all the above features, the NovaSure system has become the leading endometrial ablation product in the world, having treated over two million patients over the past decade. Over the past decade, patients have used three generations of the NovaSure endometrial ablation system, including the current handpiece, photographed here:

Given the long track record of the NovaSure system, there have been many prospective, statistical studies that track groups of patients over periods of 12 months, 36 months, and 60 months, for example. Ex. 28[1] ("Ten-year literature review of global endometrial ablation with the NovaSure device"). These studies confirm the efficacy and safety of the NovaSure system. For example, in arguable the most comprehensive, prospective study, the long-term efficacy of the

[1] Exhibit 28 refers to Exhibit 28 of the Declaration of Marc Cohn in support of Holgic's Motion for a Preliminary Injunction.

NovaSure procedure was reported over a 60-month follow-up period. *Id*. at 3 of exhibit (*i.e.*, page 271 of publication). By 60 months post-procedure, this study reported that 75% of patients had amenorrhea (a lack of any bleeding) and only 2% of patients had menorrhagia. *Id*. Given this track record, the NovaSure system has a decades-long, proven record in safety and efficacy for the treatment of menorrhagia.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my personal knowledge.

Executed this 14 day of Dec, 2015 at Marlborough, Mass.

/s/ Edward Evantash
Dr. Edward Evantash

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

JURY TRIAL DEMANDED
REDACTED PUBLIC VERSION

DEFENDANT MINERVA SURGICAL, INC.'S ANSWER TO HOLOGIC, INC.'S AND CYTYC SURGICAL PRODUCTS, LLC'S SECOND AMENDED COMPLAINT FOR INFRINGEMENT AND COUNTERCLAIMS

Defendant Minerva Surgical, Inc. ("Minerva"), by and through its undersigned attorneys, respectively submits this Answer to the Second Amended Complaint for Patent Infringement ("SAC") (D.I. 70) filed by Plaintiffs Hologic, Inc. ("Hologic") and Cytyc Surgical Products, LLC ("Cytyc") (collectively, "Plaintiffs") and Counterclaims against Plaintiffs, as follows:

NATURE OF THE ACTION

1. Minerva admits that this action involves Plaintiffs' allegations that Minerva infringes U.S. Patent Nos. 6,872,183 ("the '183 patent"), 8,998,898 ("the '898 patent"), 9,095,348 ("the '348 patent), and

9,247,989 ("the '989 patent") (collectively "the Patents-in-Suit").

THE PARTIES

2. Minerva admits only that, upon information and belief, Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Minerva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2 of the SAC, and accordingly denies the same.

3. Minerva admits only that, upon information and belief, Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Minerva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3 of the SAC, and accordingly denies the same.

4. Minerva is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the SAC, and accordingly denies the same.

5. Minerva admits that it is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

JURISDICTION AND VENUE

6. Minerva admits that the SAC purports to set forth a claim for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code. Minerva further admits that the

SAC purports to set forth claims for unfair competition arising under the Lanham Act, 15 U.S.C. § 1051 *et seq.*, and the law of the State of Delaware. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 6 of the SAC.

7. Minerva admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, and 15 U.S.C. §§ 1121(a) and 1125(a). Minerva also admits that this Court has jurisdiction over the state law claims asserted in the SAC pursuant to 28 U.S.C. § 1367, as the state law claims arise from the same common nucleus of operative facts as the federal claims.

8. Minerva admits that this Court has personal jurisdiction over Minerva as a Delaware corporation. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 8 of the SAC.

9. Minerva admits that venue is proper in this District under §§ 1391 and 1400(b) because Minerva is a Delaware corporation, but denies that this is an appropriate or convenient forum for this dispute. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 9 of the SAC.

BACKGROUND

10. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 10 of the SAC, and accordingly denies the same.

11. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 11 of the SAC, and accordingly denies the same.

12. Minerva is without knowledge or information sufficient to for a belief as to the truth of the

allegations of paragraph 12 of the SAC, and accordingly denies the same.

13. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 13 of the SAC, and accordingly denies the same.

14. Minerva admits that Exhibit A of the SAC purports to be a copy of the Minerva Endometrial Ablation System Operator's manual. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 14 of the SAC.

15. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 15 of the SAC, and accordingly denies the same.

16. Minerva denies all allegations in paragraph 16 of the SAC.

17. Minerva denies all allegations in paragraph 17 of the SAC.

18. Minerva denies all allegations in paragraph 18 of the SAC.

19. Minerva denies all allegations in paragraph 19 of the SAC.

20. Minerva admits that Dr. James Mirabile has a talk radio show on KCMO, 710 AM and 103.7 FM in the Kansas City area and on September 19, 2015 Minerva's Vice President, Eugene Skalnyi, participated in the show to discuss Minerva's Endometrial Ablation System. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 20 of the SAC.

21. Minerva admits that a podcast of the radio show is shared with physicians. Except as expressly

admitted, Minerva denies any and all remaining allegations in paragraph 21 of the SAC.

22. Minerva denies all allegations in paragraph 22 of the SAC.

23. Minerva denies all allegations in paragraph 23 of the SAC.

24. Minerva denies all allegations in paragraph 24 of the SAC.

25. Minerva admits that it provides an Operator's Manual for the Endometrial Ablation System to its physician customers and at the beginning of the Operator's Manual it states "READ ALL INSTRUCTIONS, CAUTIONS AND WARNINGS PRIOR TO USE. FAILURE TO FOLLOW ANY INSTRUCTIONS OR TO HEED ANY WARNINGS OR PRECAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY." Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 25 of the SAC.

COUNT I

(Alleged Infringement of the '183 Patent)

26. Minerva incorporates by reference the above paragraphs of this Answer.

27. Minerva admits that on its face the '183 patent entitled "System and Method for Detecting Perforations in a Body Cavity," was issued on March 29, 2005 to Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller. Minerva admits that Exhibit B of the SAC purports to be a true and correct copy of the '183 patent. Minerva denies any and all remaining allegations in paragraph 27 of the SAC.

28. Minerva admits only that, upon information and belief, Cytyc claims to have assigned the '183

patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the SAC, and on that basis, denies them.

29. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the SAC, and on that basis, denies them.

30. Minerva admits that it had knowledge of the '183 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 30 of the SAC.

31. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 31 of the SAC.

32. Minerva denies all allegations in paragraph 32 of the SAC.

33. Minerva denies all allegations in paragraph 33 of the SAC.

34. Minerva denies all allegations in paragraph 34 of the SAC.

35. Minerva denies all allegations in paragraph 35 of the SAC.

36. Minerva denies all allegations in paragraph 36 of the SAC.

COUNT II
(Alleged Infringement of the '898 Patent)

37. Minerva incorporates by reference the above paragraphs of this Answer.

38. Minerva admits that Plaintiffs purport that the '898 patent entitled "Moisture Transport System for

Contact Electrocoagulation," was issued on April 7, 2005 to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, Estela Hilario, and David C. Auth. Minerva admits that Exhibit C of the SAC purports to be a true and correct copy of the '898 patent. Minerva denies any and all remaining allegations in paragraph 38 of the SAC.

39. Minerva admits only that, upon information and belief, Cytyc claims it assigned the '898 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 39 of the SAC, and on that basis, denies them.

40. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the SAC, and on that basis, denies them.

41. Minerva admits that it had knowledge of the '898 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 41 of the SAC.

42. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 42 of the SAC.

43. Minerva denies all allegations in paragraph 43 of the SAC.

44. Minerva denies all allegations in paragraph 44 of the SAC.

45. Minerva denies all allegations in paragraph 45 of the SAC.

46. Minerva denies all allegations in paragraph 46 of the SAC.

47. Minerva denies all allegations in paragraph 47 of the SAC.

COUNT III
(Alleged Infringement of the '348 Patent)

48. Minerva incorporates by reference the above paragraphs of this Answer.

49. Minerva admits that Plaintiffs purport that the '348 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on August 5, 2015 to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, and Estela Hilario. Minerva admits that Exhibit D of the SAC purports to be a true and correct copy of the '348 patent. Minerva denies any and all remaining allegations in paragraph 49 of the SAC.

50. Minerva admits only that, upon information and belief, Cytyc claims to have assigned the '348 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 50 of the SAC, and on that basis, denies them.

51. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the SAC, and on that basis, denies them.

52. Minerva admits that it had knowledge of the '348 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 52 of the SAC.

53. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 53 of the SAC.

54. Minerva denies all allegations in paragraph 54 of the SAC.

55. Minerva denies all allegations in paragraph 55 of the SAC.

56. Minerva denies all allegations in paragraph 56 of the SAC.

57. Minerva denies all allegations in paragraph 57 of the SAC.

58. Minerva denies all allegations in paragraph 58 of the SAC.

COUNT IV
(Alleged Unfair Competition Under
15 U.S.C. § 1125(a))

59. Minerva incorporates by reference the above paragraphs of this Answer.

60. Minerva denies all allegations in paragraph 60 of the SAC.

61. Minerva admits that Minerva markets and/or sells its Endometrial Ablation System in the United States and travels in interstate commerce. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 61 of the SAC.

62. Minerva denies all allegations in paragraph 62 of the SAC.

63. Minerva denies all allegations in paragraph 63 of the SAC.

64. Minerva denies all allegations in paragraph 64 of the SAC.

65. Minerva denies all allegations in paragraph 65 of the SAC.

66. Minerva denies all allegations in paragraph 66 of the SAC.

67. Minerva denies all allegations in paragraph 67 of the SAC.

COUNT V
(Alleged Deceptive Trade Practice Under
6 Del. C. § 2532)

68. Minerva incorporates by reference the above paragraphs of this Answer.

69. Minerva denies all allegations in paragraph 69 of the SAC.

70. Minerva denies all allegations in paragraph 70 of the SAC.

71. Minerva denies all allegations in paragraph 71 of the SAC.

72. Minerva denies all allegations in paragraph 72 of the SAC.

73. Minerva denies all allegations in paragraph 73 of the SAC.

74. Minerva denies all allegations in paragraph 74 of the SAC.

75. Minerva denies all allegations in paragraph 75 of the SAC.

76. Minerva denies all allegations in paragraph 76 of the SAC.

77. Minerva denies all allegations in paragraph 77 of the SAC.

COUNT VI
(Alleged Unfair Competition–Delaware Common Law)

78. Minerva incorporates by reference the above paragraphs of this Answer.

79. Minerva denies all allegations in paragraph 79 of the SAC.

80. Minerva denies all allegations in paragraph 80 of the SAC.

81. Minerva denies all allegations in paragraph 81 of the SAC.

82. Minerva denies all allegations in paragraph 82 of the SAC.

83. Minerva denies all allegations in paragraph 83 of the SAC.

84. Minerva denies all allegations in paragraph 84 of the SAC.

85. Minerva denies all allegations in paragraph 85 of the SAC.

86. Minerva denies all allegations in paragraph 86 of the SAC.

87. Minerva denies all allegations in paragraph 87 of the SAC.

COUNT VII
(Alleged Tortious Interference With A Business Relationship–Delaware Common Law)

88. Minerva incorporates by reference the above paragraphs of this Answer.

89. Minerva denies all allegations in paragraph 89 of the SAC.

90. Minerva denies all allegations in paragraph 90 of the SAC.

91. Minerva denies all allegations in paragraph 91 of the SAC.

92. Minerva denies all allegations in paragraph 92 of the SAC.

93. Minerva denies all allegations in paragraph 93 of the SAC.

94. Minerva denies all allegations in paragraph 94 of the SAC.

95. Minerva denies all allegations in paragraph 95 of the SAC.

96. Minerva denies all allegations in paragraph 96 of the SAC.

97. Minerva denies all allegations in paragraph 97 of the SAC.

COUNT VIII
(Alleged Infringement of the '989 Patent)

98. Minerva incorporates by reference the above paragraphs of this Answer.

99. Minerva admits that on its face the '989 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on February 2, 2016 to Csaba Truckai. Minerva admits that Exhibit H of the SAC purports to be a true and correct copy of the '989 patent. Minerva denies any and all remaining allegations in paragraph 99 of the SAC.

100. Minerva admits that Cytyc purports to be the assignee and lawful owner of all right, title, and interest in and to the '989 patent. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 100 of the SAC, and on that basis, denies them.

101. Minerva admits that it had knowledge of the '989 patent prior to the filing of the SAC. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 101 of the SAC.

102. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted,

Minerva denies any and all remaining allegations in paragraph 102 of the SAC.

103. Minerva denies all allegations in paragraph 103 of the SAC.

104. Minerva denies all allegations in paragraph 104 of the SAC.

105. Minerva denies all allegations in paragraph 105 of the SAC.

106. Minerva denies all allegations in paragraph 106s of the SAC.

PRAYER FOR RELIEF

1. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 1.

2. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 2.

3. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 3.

4. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 4.

5. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 5.

6. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 6.

7. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 7.

8. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 8.

9. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 9.

10. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 10.

11. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 11.

12. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 12.

13. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 13.

14. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 14.

15. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 15.

16. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 16.

17. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 17.

18. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 18.

19. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 19.

20. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 20.

21. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 21.

AFFIRMATIVE DEFENSES

In addition to the affirmative defenses described below, subject to its responses above, Minerva specifically reserves all rights to allege additional affirmative defenses that become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE
(Failure to State Claim)

107. The SAC fails to state a claim for which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Noninfringement)

108. Minerva is not infringing and has not infringed, directly, by inducement, contributorily or in any other way, any claim of the '183, '898, '348, and '989 patents.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

109. One or more asserted claims of the '183, '898, '348, and '989 patents are invalid for failing to meet the conditions for patentability in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112.

FOURTH AFFIRMATIVE DEFENSE
(Estoppel)

110. The claims of '183, '898, '348, and '989 patents are and were limited by amendment, the prior art, and/or by the statements made during their prosecution before the U.S. Patent and Trademark Office ("USPTO") such that Plaintiffs are now estopped and/or otherwise precluded from maintaining that such claims of the '183, '898, '348, and '989 patents are of sufficient scope to cover the accused products either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE
(Failure to Mark and Limitation on Damages)

111. Plaintiffs' claim for damages is barred in whole or in part by failure to provide adequate notice under

35 U.S.C. § 287. Any claim for damages for patent infringement is limited to only those damages occurring after the notice of infringement and, in any event, by 35 U.S.C. § 286.

SIXTH AFFIRMATIVE DEFENSE
(No Right to Injunctive Relief)

112. Plaintiffs are not entitled to injunctive relief because any injury to Plaintiffs is not immediate or irreparable, and Plaintiffs have an adequate money remedy for any claim that they can prove.

SEVENTH AFFIRMATIVE DEFENSE
(Safe Harbor)

113. There is no infringement—directly, by inducement, contributorily or in any other way—of any valid claim of the '183, '898, '348, and '989 patents by Minerva for any allegedly infringing activities falling within the safe harbor under 35 U.S.C. § 271(e).

EIGHTH AFFIRMATIVE DEFENSE
(Laches)

114. Plaintiffs' claims against Minerva regarding the '183, '898, '348, and '989 patents are barred, in whole or in part, by 35 U.S.C. § 286 and/or the doctrine of laches.

NINTH AFFIRMATIVE DEFENSE
(Obviousness-Type Double Patenting)

115. The asserted claims of the '348 and '989 patents are subject to the doctrine of obviousness-type double patenting. In order to issue, the asserted claims of the '348 and '989 patents should have been subject to a terminal disclaimer setting their respective expiration date as April 12, 2016.

TENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

116. Plaintiffs' claims are barred by the doctrine of unclean hands, the facts and circumstances of which are generally described in Minerva's counterclaims below, including Plaintiffs filing this lawsuit in bad faith and making false and misleading statements related to Minerva and Minerva's products.

ELEVENTH AFFIRMATIVE DEFENSE
(Lack of Standing)

117. Plaintiff Hologic lacks standing to assert any claims relating to the '183, '898, '348 and '989 patents because it did not have sufficient rights in the asserted patents at the time the suit was filed.

COUNTERCLAIMS

PARTIES

118. Minerva hereby pleads the following counterclaims against Plaintiffs.

119. Minerva is a corporation organized under the laws of Delaware, having its principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

120. On information and belief, based on Plaintiffs' allegations, Hologic is a corporation organized and existing under the laws of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752 and Cytyc is a limited liability company organized and exiting under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752.

JURISDICTION AND VENUE

121. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

122. Plaintiffs are subject to personal jurisdiction in this judicial district because Plaintiffs availed themselves of the jurisdiction of this Court and engaged in acts giving rise to this controversy in this district.

123. Venue is appropriate in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

124. Since the company's formation in 2008, Minerva has been dedicated to developing and bringing to market new technology that would significantly advance the treatment of abnormal uterine bleeding ("AUB"). To date, Minerva has raised tens of millions from private investors to fund this singular purpose and, having received FDA clearance in July 27, 2015, Minerva is at a critical inflection point for its survival as it begins to commercialize the technology that has been under development for years.

125. Hologic has been well-aware of Minerva's technology and its work since 2009 and has spent years preparing for Minerva's launch. In anticipation of the entrance of new endometrial ablation technology—the first in 15 years—Hologic prepared and is now executing an anti-competitive, no-holds-barred campaign against Minerva that is designed to stamp-out any competition and to prevent Minerva from gaining any traction in the market whatsoever. In doing so, Hologic has gone too far in employing a host of unfair business practices, including the dissemination of false and misleading statements in

the marketplace to customers and prospective customers that were carefully designed to permanently and irreparably harm and malign Minerva, its technology, and its employees.

126. Hologic does so not to protect patients or the physicians that treat them, or to fairly engage on the merits competing products, but to protect its market-share at all costs—NovaSure® generates [redacted] for Hologic.

127. As Hologic is well-aware, the FDA-approved clinical studies demonstrate that Minerva is a safe, effective product. Indeed, clinical studies demonstrated the following efficacy rates in comparison to the Objective Performance Criteria ("OPC") (*i.e.*, combined rates of other endometrial ablation devices approved by FDA) of 66%, which include NovaSure®:

	"Success" (Less than normal bleeding- PBLAC < 75)	**Amenorrhea (Zero bleeding)**	**Adverse Events (>2 Weeks–1 Year)**	**Recom-mend to a Friend**	**Average Procedure Time**
Minerva	91.8%	66.4%	0%	99%	3.9 minutes
NovaSure®	77.7%	36%	12%	95%	5 minutes

128. Minerva achieved these significant results by developing new endometrial ablation technology using scientific advancement and innovation as well as by drawing on the years of experience that its founders

and executives have in this field—several of whom were the original inventors and developers of the NovaSure® technology. Knowing that Minerva's technology was a significant advancement and that its business and scientific team were well-respected innovators, Hologic took note of this rising threat more than six years before a single Minerva unit was sold in the market.

129. [redacted]

130. [redacted]

131. In addition, Hologic has employed a number of business practices designed to unfairly inhibit Minerva's ability to compete in the marketplace, including the dissemination of false and/or misleading statements to customers and prospective customers of Minerva. These unfair business practices began in anticipation of Minerva's entry to the market, and have continued since then.

132. Even before Minerva's system was launched, Hologic began disseminating false and deceptive messages about the safety and technological attributes of Minerva's system. Since then, Hologic has approached and continues to approach physicians and hospital administrators who have used, expressed interest in and/or are potential customers of Minerva's system, with a false and deceptive message that physicians should not use Minerva's system because the device is unsafe for patients.

a. [redacted]

[redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. On February 15, 2015, Minerva formally demanded that Hologic cease and desist from continuing its misleading campaign and to provide a corrective disclosure to those physicians who had exposed to Hologic's false and misleading statements about Minerva and its system. On February 25, 2016, Hologic denied knowledge of any such false or misleading conduct and did not agree to correct its prior statements.

133. On information and belief, Hologic has made and continues to make false and misleading statements about other aspects of Minerva's system, including that the system (i) is associated with a high number of adverse events (contrary to the findings in Minerva's FDA-approved clinical studies); (ii) is associated with a high number of injuries to patients "all over the country"; and (iii) cannot be used in ablation procedures where the patient must first undergo certain other treatments (*e.g.*, removal of polyps or fibroids).

134. Hologic also presents physicians with misleading information about the efficacy of Hologic's NovaSure® device, including on its product label, in articles/advertising sponsored by Hologic, and in direct communications. Since learning the results of Minerva's clinical trials, including efficacy and amenorrhea rates of 91.8% and 66.4% respectively, Hologic continues to depart from the FDA approved results of the NovaSure® clinical study utilized for FDA approval, by advertising on the NovaSure® website that, "The NovaSure® procedure is effective: For 90% of women, menstrual bleeding is dramatically reduced or stopped." The FDA-approved results state efficacy rates of 77.7% (Success rate) and 36% (Amenorrhea or zero bleeding rate). Hologic also advertises that the hysterectomy rate over the five

years following the NovaSure® treatment is less than 3%, when the FDA-approved hysterectomy rate over just three years is 6.3%. Minerva is informed and believes that Hologic has not submitted any supplemental study to the FDA for approval of the improved claims. At the same time, Hologic without basis, mischaracterizes and disparages the results of Minerva's clinical study. In doing so, Hologic is in not only in violation of FDA labeling laws, but is also engaged in deceptive advertising under state law, including the law of Delaware.

FIRST COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '183 Patent)

135. Minerva realleges and incorporates by reference the foregoing paragraphs.

136. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '183 patent.

137. Plaintiffs have charged in the SAC that one or more claims of the '183 patent have been infringed by Minerva.

138. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '183 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '183 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

139. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '183

patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

140. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '183 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '898 Patent)

141. Minerva realleges and incorporates by reference the foregoing paragraphs.

142. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '898 patent.

143. Plaintiffs have charged in the SAC that one or more claims of the '898 patent have been infringed by Minerva.

144. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '898 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '898 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

145. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '898 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

146. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '898 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '348 Patent)

147. Minerva realleges and incorporates by reference the foregoing paragraphs.

148. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '348 patent.

149. Plaintiffs have charged in the SAC that one or more claims of the '348 patent have been infringed by Minerva.

150. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '348 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '348 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

151. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '348 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

152. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '348 patent.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement
of the '989 Patent)

153. Minerva realleges and incorporates by reference the foregoing paragraphs.

154. Plaintiffs allege in the SAC that Cytyc is the owner of all rights, title, and interest in the '989 patent.

155. Plaintiffs have charged in the SAC that one or more claims of the '989 patent have been infringed by Minerva.

156. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '989 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '989 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

157. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '989 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

158. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '989 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '183 Patent)

159. Minerva realleges and incorporates by reference the foregoing paragraphs.

160. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '183 patent.

161. Each and every claim of the '183 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

162. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '183 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

163. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '183 patent are invalid.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '898 Patent)

164. Minerva realleges and incorporates by reference the foregoing paragraphs.

165. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '898 patent.

166. Each and every claim of the '183 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes,

including but not limited to §§ 101, 102, 103, and/or 112.

167. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '898 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

168. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '898 patent are invalid.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '348 Patent)

169. Minerva realleges and incorporates by reference the foregoing paragraphs.

170. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '348 patent.

171. Each and every claim of the '348 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

172. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '348 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

173. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '348 patent are invalid.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Invalidity
of the '989 Patent)

174. Minerva realleges and incorporates by reference the foregoing paragraphs.

175. Plaintiffs allege in the SAC that Cytyc is the owner of all rights, title, and interest in the '989 patent.

176. Each and every claim of the '989 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

177. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '989 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

178. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '989 patent are invalid.

NINTH COUNTERCLAIM
(Unfair Competition Under 15 U.S.C. § 1125(a) & (c))

179. Minerva realleges and incorporates by reference the foregoing paragraphs.

180. Hologic has used a false or misleading description of facts in connection with its marketing and sale of the NovaSure® device.

181. Hologic markets and/or sells the NovaSure® device throughout the United States and travels in interstate commerce.

182. Hologic's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing and potential Minerva customers about the relative characteristics of the NovaSure® and Minerva devices.

183. Hologic's conduct has caused further harm to Minerva in the form of tarnishment of Minerva, its device and its mark.

184. Hologic's conduct constitutes unfair competition in violation of 15 U.S.C. § 1125(a) and (c).

185. As a result of Hologic's false description of facts, Minerva has suffered and continues to suffer damages, including loss of sales.

186. Hologic's false and misleading description of facts is willful, making this an exceptional case entitling Minerva to recover Hologic's profits of sales of NovaSure®, actual and enhanced damages, and costs Minerva incurred in prosecuting its claims, pursuant to 15 U.S.C. § 1117(a) and (c).

187. Hologic's false and misleading description has caused and will continue to cause irreparable harm to Minerva for which there is no adequate remedy at law, unless the Court enjoins Hologic's false and misleading statements pursuant to 15 U.S.C. § 1116(c).

TENTH COUNTERCLAIM
(Deceptive Trade Practices Under 6 Del. C. § 2532)

188. Minerva realleges and incorporates by reference the foregoing paragraphs.

189. Hologic in the course of its business, has engaged and continues to engage in conduct that disparages the Minerva system, including without

limitation, but and through its false and misleading representation that the Minerva system is unsafe [redacted]

190. Hologic in the course of its business, has engaged and continues to engage in conduct that causes a likelihood of confusion or misunderstanding about the Minerva system, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [redacted]

191. Hologic in the course of its business, by and through its false and misleading representations of fact, has engaged and continues to engage in deceptive trade practices in violation of 6 Del. C. § 2532, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [redacted]

192. As a result of Hologic's conduct, Minerva has suffered and continues to suffer damages, including loss of sales.

193. Equity favors enjoining Hologic's conduct pursuant to 6 Del. C. § 2533(a).

194. Hologic's conduct has been and is willful such that Minerva is entitled to its attorneys' fees and costs.

195. Minerva is entitled to damages under Delaware common law thereby entitling Minerva to treble damages under 6 Del. C. § 2533(c).

ELEVENTH COUNTERCLAIM
(Unfair Competition–Delaware Common Law)

196. Minerva realleges and incorporates by reference the foregoing paragraphs.

197. Minerva had a reasonable expectancy of entering and continuing valid business relationships with existing and potential customers.

198. Hologic has wrongfully interfered with Minerva's existing and potential business relationships by approaching customers that were using, interested in and/or potential customers of Minerva's system and [redacted] (ii) making false and misleading statements of fact regarding the contraindications of Minerva's system; (iii) disparaging Minerva's system, Minerva, and its employees; (iv) making false and misleading statements about the efficacy of Hologic's NovaSure® device; and [redacted]

199. Hologic has used and continues to use false and/or misleading descriptions of facts in connection with its marketing and/or sale of the NovaSure® system.

200. Hologic's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing and potential customers of Minerva about the relative characteristics of the NovaSure® and Minerva devices.

201. Hologic's conduct has caused and continues to be undertaken with the purpose of deceiving

customers and appropriating Minerva's business relationships, goodwill, and competitive advantages.

202. Hologic's conduct constitutes unfair competition under the common law, including without limitation by its activities in Delaware.

203. As a result of Hologic's misconduct, Minerva has suffered and continues to suffer economic harm, including loss of sales. As a result of Hologic's misconduct, Hologic has caused and will continue to cause customer confusion or misunderstanding and has caused and will continue to cause damage to Minerva's goodwill with customers and potential customers.

204. Hologic's misconduct has caused and will continue to cause irreparable harm to Minerva for which there is no adequate remedy at law, unless its conduct is enjoined.

TWELFTH COUNTERCLAIM
(Interference with Contract/Business Advantage)

205. Minerva realleges and incorporates by reference the foregoing paragraphs.

206. Minerva had a reasonable expectancy of entering and continuing valid business relationships with existing and prospective customers as well as others, including clinical investigators under contract with Minerva.

207. On information and belief, Hologic had knowledge of Minerva's business relationships and prospective customers as Hologic has been tracking Minerva's activity, including the whereabouts of its sales staff, since before Minerva's system was commercially available and all times since.

208. Hologic has intentionally interfered with Minerva's existing and potential business relationships by approaching customers that were using, interested in and/or potential customers of Minerva's system and (i) making false and misleading statements of fact regarding the safety of Minerva's system, [redacted] (ii) making false and misleading statements of fact regarding the contraindications of Minerva's system; (iii) disparaging Minerva's system, Minerva, and its employees; (iv) making false and misleading statements about the efficacy of Hologic's NovaSure® device; and (v) [redacted]

209. Hologic, by and through its false and misleading statements and conduct, has engaged and in and continues to engage in wrongful conduct in violation of federal and state law, including 15 U.S.C. § 1125 and 6 Del. C. § 2532.

210. Hologic's conduct constituted tortious interference with a business relationship under the common law, including without limitation its activities in Delaware.

211. As a result of Hologic's intentional interference, Minerva has suffered and continues to suffer economic harm, including loss of sales.

212. Hologic's actions and conduct are willful and undertaken with the purpose of deceiving customers.

213. Hologic's intentional interference has caused and will cause irreparable harm to Minerva for which

there is no adequate remedy at law, unless the conduct is enjoined.

THIRTEENTH COUNTERCLAIM
(Breach of Contract)

214. Minerva realleges and incorporates by reference the foregoing paragraphs.

215. [redacted]

216. [redacted]

217. [redacted]

218. [redacted]

219. [redacted]

220. [redacted]

FOURTEENTH COUNTERCLAIM
(Trade Libel)

221. Minerva realleges and incorporates by reference the foregoing paragraphs.

222. Through systematic communications and misrepresentation made by Plaintiffs, Plaintiffs have intentionally published and perpetuated false and malicious statements about Minerva.

223. Plaintiffs' statements are false and were known by Plaintiffs to be false when made.

224. Plaintiffs have made statements about Minerva willfully, with intent to disparage Minerva, and the products offered for sale by Minerva.

225. Plaintiffs' statements were made with the intent and knowledge that individuals and entities with whom Minerva dealt would cease its business dealings with Minerva.

226. Plaintiffs' conduct has caused, and if allowed to continue will continue to cause, Minerva to suffer substantial irreparable injury, for which there is no adequate remedy at law.

227. Minerva has suffered damages as a result of Plaintiffs' actions, including but not limited to a loss of revenue, profits, goodwill, and future earnings.

JURY DEMAND

Minerva demands a trial by jury on all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Minerva respectfully requests that the Court enter judgment as follows:

A. A judgment in favor of Minerva on all of its Counterclaims;

B. Dismissal of all of Plaintiffs' claims in their entirety with prejudice;

C. A judgment that Plaintiffs take nothing by their Second Amended Complaint;

D. A declaration that Minerva does not infringe, directly or indirectly, literally or by the doctrine of equivalents, any valid enforceable claims of the '183, '898, '348, and '989 patents;

E. A declaration that each and every claim of the '183, '898, '348, and '989 patents is invalid;

F. Awarding damages to Minerva for tortuously interfering with Minerva's business relationships and for unfairly competing with Minerva under both Federal and Delaware law;

G. Awarding damages to Minerva for breach of contract;

H. An order preliminarily and permanently enjoining Plaintiffs, their affiliates and subsidiaries, and each of their officers, agents, servants and employees and those acting in privity of concert with them, from:

i. Threatening to assert or otherwise attempt to enforce the '183, '898, '348, and '989 patents against Minerva, its customers, suppliers, or anyone in privity with Minerva;

ii. Distributing or using any advertising, promotional material, sales material, solicitations, or mailing (electronic or otherwise), or making any statement to its customers, potential customers or suppliers, which contains an express or implied claim that Minerva has infringed or is infringing the '183, '898, '348, and '989 patents unless and until

there is such a judgment of infringement against Minerva;

iii. Using this action or any other lawsuit between any of the parties to this action to solicit business for Plaintiffs;

iv. Soliciting or accepting orders from a customer using the false and or misleading advertising or unfair competitive statements discussed herein, or any other advertising or statements containing similar false or misleading claims;

v. Using false and/or misleading representations or descriptions in commerce that are likely to cause confusion regarding the characteristics of Minerva's accused system;

vi. Using false and/or misleading representations or descriptions in commerce that interfere with or are likely to injure Minerva's business relations;

vii. Unfairly competing with Minerva; and

viii. Committing any acts which are likely to injure Minerva's business reputation.

I. A judgment that this is an "exceptional case" and an award of Minerva's reasonable attorneys' fees, expenses, and costs in this action under 35 U.S.C. § 285; and

J. An award of such other relief as the Court may deem appropriate and just under the circumstances.

Respectfully submitted,

ROSS ARONSTAM & MORITZ LLP

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Dated: March 4, 2016

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,
v.
MINERVA SURGICAL, INC.,
Defendant.

JURY TRIAL DEMANDED
FILED UNDER SEAL

DECLARATION OF DR. EVGUENI SKALNYI M.D. IN SUPPORT OF DEFENDANT MINERVA SURIGICAL, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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Dated: March 11, 2016

I, Evgueni Skalnyi, M.D., the undersigned, state and declare as follows:

A. Qualifications

1. I am employed by Minerva Surgical, Inc. ("Minerva"). I have worked at Minerva for over 5 years. My current title is Vice President Medical Affairs.

2. I am a trained Gynecologist. I am over twenty-one years of age, and unless otherwise stated, I have personal knowledge of the facts set out in this declaration, and if called upon to testify, I could and would testify competently regarding these facts.

3. I earned my Medical Degree from State University of Medicine and Pharmacy Nicolae Testemitanu in 1988. I worked as a practicing Obstetrician/ Gynecologist, served as an Associate Professor at Department of Obstetrics and Gynecology at State University of Medicine and Pharmacy Nicolae Testemitanu. After my immigration to the United States I worked as a Clinical Instructor at the Stanford University Endoscopy Center, followed by a number of positions in a variety of medical device companies. During all these years I became intimately familiar with endometrial ablation. I personally performed, taught and supported thousands of endometrial ablation procedures in USA, Canada, UK, Germany, The Netherlands, Norway, Hungary, Mexico, Australia, New Zealand, and many other countries. I made numerous scientific presentations on this subject at a variety of national and international specialty meetings and congresses. For over a decade I serve as an AdHoc reviewer at the Journal of Minimally Invasive Gynecology. In 2011 I became and currently serve as a Member of the Editorial Advisory Board for the same Journal. I was the architect of a

significant number of clinical research efforts, including studies performed under the FDA's Investigational Device Exemption (IDE) regulations. Outcomes of these research efforts were published in many reputable specialty peer-reviewed Journals. I have personal experience using both the NovaSure system and Minerva's Endometrial Ablation System ("EAS") on live patients, and have used earlier technology – including the roller ball, when the NovaSure and Minerva Systems were not available.

4. In 1998 I joined Novacept and was a key participant in the group that designed, developed and commercialized the NovaSure system. After acquisition of Novacept by Cytyc in 2004, I joined Cytyc and served in the capacity of Vice President of Medical Affairs at Cytyc Surgical Products until the transfer of the company to Hologic in 2007. I was never employed by Hologic in any capacity.

5. I am very familiar with the clinical testing conducted to support FDA approval of both the NovaSure and Minerva endometrial ablation devices, as well as the true clinical value of such data. I am also well aware of the differences between the clinical research needed to support FDA approval of endometrial ablation devices and other post-approval research efforts. I am generally very familiar with most of the intricacies of the NovaSure technology, steps of the procedure, etc. I have educated thousands of doctors in the NovaSure procedure, as well as prepared many to serve as educators, speakers, and trainers for NovaSure. I am also very familiar with most of the intricacies of the Minerva EAS technology, steps of the procedure, etc. I have also educated doctors in the use of the Minerva EAS.

B. The Condition

6. About 10 million American women suffer from menorrhagia (excessive and often painful menstrual bleeding) each year. Many women begin to experience heavy and/or irregular bleeding in their 30s and 40s, as they begin to get closer to menopause. Heavy periods are more than just an annoyance—they can take a physical, social, and emotional toll as well. Menorrhagia can be a debilitating condition that can negatively impact a woman's quality of life. Between 15-20% of healthy women experience debilitating menorrhagia that interferes with their normal activities. In the absence of a better and less invasive alternative, in the 1990s the most common treatment available to such women was a hysterectomy (removal of the uterus).

7. Uterine ablation, also referred to as endometrial ablation, is an in-office procedure performed by a trained physician to lighten or stop heavy periods in woman with menorrhagia. It is performed by ablating (destroying) the endometrial lining of the uterine cavity using a variety of techniques (Radio frequency, or RF, energy, thermal energy including heat or cold). Endometrial ablation techniques are divided into two broad categories: First and Second Generation. First Generation technologies, Nd:YAG laser (Goldrath 1981) and the rollerball technique (Vancaillie 1996 ablation), were developed starting in the 1980's. Although efficacious, these technologies are associated with a significant learning curve and have a higher incidence of intra-operative adverse events: uterine perforation, hemorrhage, fluid intra-vasation, hyponatremia, encephalopathy, death (Hulka 1993).

8. Due to the significant complexity of First Generation endometrial ablation systems, Second

Generation endometrial ablation technologies were developed. There are currently six endometrial ablation systems approved by the FDA (ThermaChoice UBT®, HydroThermablator® (HTA)–Her Option®, NovaSure®, MEA, and Minerva's EAS) and five are commercially available in the U.S. (ThermaChoice UBT®, HydroThermablator® (HTA)–Her Option®, NovaSure®, and Minerva's EAS). These new technologies are generally faster, less complex and, in most cases, allow for a significant reduction in the incidence of complications associated with endometrial ablation when compared to the First Generation "Gold Standard," namely, rollerball ablation. These Second Generation technologies allow the average gynecologist to offer a less invasive treatment option for his or her patients with menorrhagia. These Second Generation technologies include the use of heated liquid, either contained within a balloon inflated in the uterus (ThermaChoice) or instilled directly into the uterus (HTA). Others employ the use of super-low temperatures (Her Option). Yet others employ RF energy (NovaSure) or microwave energy (MEA) to achieve endometrial tissue destruction. There is a significant body of scientific evidence demonstrating the safety and effectiveness of all of these systems relative to the First Generation systems.

C. The NovaSure System

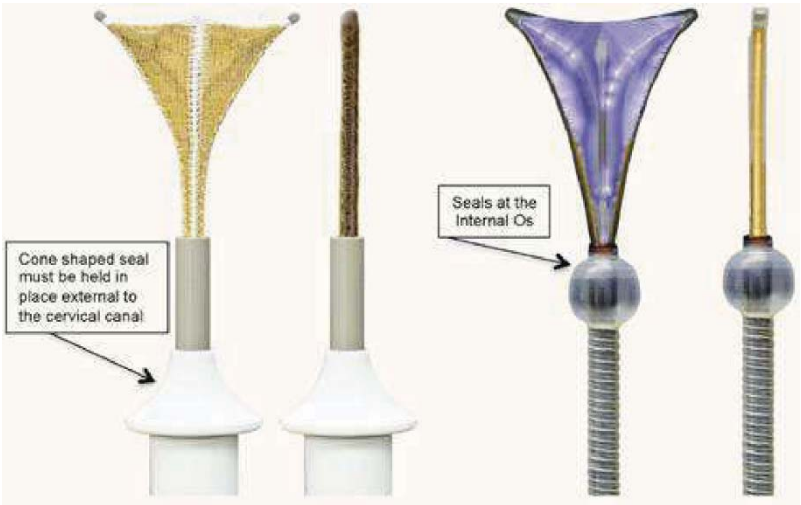
9. The founder of Minerva, Mr. Csaba Truckai, also founded Novacept Corporation in 1996. The Novacept design team, which included Mr. Truckai, and with whom I worked: (i) conceived of the original NovaSure design; (ii) filed the Pre-Market Approval ("PMA") with the FDA for the NovaSure system; (iii) performed the necessary R&D, including clinical trials; (iv) filed the first patent applications relating to

the NovaSure design; (v) obtained FDA approval for the NovaSure in 2001; (vi) established the market for NovaSure; and (vii) significantly expanded the endometrial ablation market with approximate annual revenues in 2002 of $18M, 2003 of $36M, and revenues in 2004 of $78M, the year Novacept was acquired by Cytyc Corporation. D.I. 13-1 (2004 Merger Agreement).

10. The NovaSure system's Success Rate, based on the Summary of Safety and Effectiveness Data (SSED) issued by the FDA upon approval of the device, is 77.7%. Ex. 5 at MSI00017058. Also, the NovaSure system's Amenorrhea Rate according to the same SSED is 36.0%. *Id*.

11. Although back in 2001 the NovaSure system provided benefits that practitioners favored over the existing alternatives at the time, such as the roller-ball, like any technology, the NovaSure had its drawbacks as well. Minerva's design team includes not only Mr. Truckai, but

* * *



Any visual similarity to the devices, i.e., an elongated "Y", is a consequence of the anatomical shape and position of the uterus within the human body.

19. Hologic states that I "suggested" in a podcast that Minerva's system provides the "same benefits" as the NovaSure system. Mot. 7. I did not say or suggest that Minerva's system provides the same benefits, nor does Hologic say at what point in the roughly hour-long program I said anything about the "same benefits." I strongly disagree with Hologic' statement. What I discussed is how the Minerva EAS provides superior results and advantages above and beyond other treatment alternatives. I reviewed the podcast and, if anything, in the podcast I state that the current Minerva team is and was aware of the detriments and weaknesses of the NovaSure and other systems. The discussion is about positives and negatives of all currently available endometrial ablation systems and how the Minerva EAS was designed to be better by addressing the drawbacks of existing (older) designs. D.I. 24 (podcast at approx. 23 minutes).

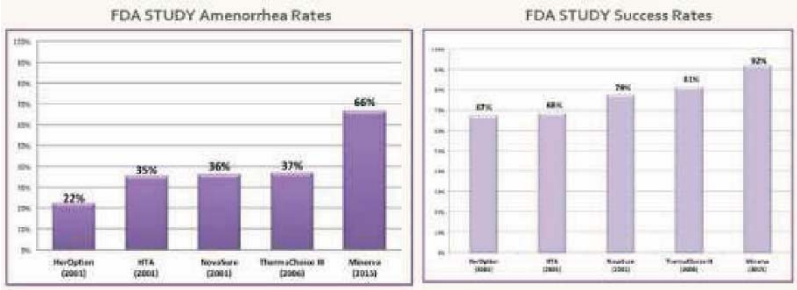
E. Clinical Studies Required For FDA Approval

20. Two measurements used by the FDA when evaluating the efficacy of endometrial ablations systems are (i) Success Rate (i.e., reducing menstrual bleeding to a level that is normal or below normal) and (ii) Amenorrhea Rate (i.e., reducing excessive menstrual bleeding to zero). Minerva conducted two separate clinical studies that were submitted to the FDA, and are the basis for FDA approval.

21. The first study begun in June 2011 was the "Minerva Single Arm Study." The Single Arm Study compared Minerva's efficacy to an Objective Performance Criteria (OPC) control group comprised of

the combined Success Rates of all previously FDA approved endometrial ablation products (ThermaChoice, Her Option, HTA, NovaSure, MEA).

E.g., Ex. 10 at MSI00004515.



Minerva's Success Rate based on its FDA issued Summary of Safety and Effectiveness Data (SSED) is 91.8%, which is statistically significantly superior to the OPC results. Ex. 6 at MSI00017115. The Minerva Single Arm Study Amenorrhea Rate (zero bleeding) according to the same SSED was 66.4%. *Id*. In the chart below, I contrast Minerva's FDA-reported Success and Amenorrhea Rates reported in the Minerva Single Arm Study with the FDA-reported Success and Amenorrhea Rates for the NovaSure system:

FDA- Reported Rates	NovaSure System[1]	Minerva EA[2]S
Success Rate	77.7%	91.8%
Amenorrhea Rate	36.0%	66.4%

22. The second study, the Minerva "Randomized Study," began in March 2012. The Randomized Study compared effectiveness results (Success Rate and

[1] Ex. 5 at MSI00017058.

[2] Ex. 6 at MSI00017115.

Amenorrhea Rate) of Minerva patients with a control group that were treated with Rollerball ablation, which was the same control group assigned by the FDA to all previous FDA clinical studies of endometrial ablation devices, including NovaSure. Minerva's Success Rate of 93.1% in this second study was statistically significantly superior to the Rollerball Success Rate of 80.4%. In addition, the Minerva Amenorrhea Rate (zero bleeding) was 71.6% when compared to the Rollerball Amenorrhea Rate of 49%. Importantly, Minerva is the first product in history to be statistically significantly superior to the "Gold Standard" Rollerball ablation in FDA approved clinical studies. In both of the above studies, Minerva's system achieved the highest efficacy rates in the endometrial ablation field in FDA clinical trial history.

F. Benefits of the Minerva EAS

23. Unlike the NovaSure handpiece, Minerva's EAS design uses a Plasma Forming Array (PFA) and fluid-tight sealed silicone membrane to accomplish the ablation, among many other distinct features. Minerva's PFA glows a bright blue during operation. Exs. 7 (PFA in operation), 19 (PFA in saline), 15 (PFA in egg white). Minerva's use of its PFA technology has numerous benefits over other existing designs, including the NovaSure System. Some of these benefits are described in Minerva documentation. E.g., Ex. 10 at MSI00004516-17.

24. For example, Minerva's PFA uses a thermally-conductive sealed silicone membrane to heat the uterine tissue more gently than older devices including the NovaSure system. The smooth silicon membrane results in easier insertion and removal. Minerva's design also results in easier deployment with a reduced requirement for perfect positioning

within the uterus; better ablation of cavities with irregularities; and the ablation is performed using a significantly lower power level (approximately a quarter of the power required to perform an ablation with the NovaSure). It is desirable to deliver less power (i.e., voltage times current) into the patient's body, rather than more power. Minerva's lower power requirement also results in a more comfortable procedure for the patient, which translates to generally less anesthesia having to be used, which in itself is a benefit to the patient. Minerva's lower power requirement also results in a (anecdotally reported) more comfortable procedure for the patient, which translates to generally less anesthesia having to be used, which in itself is a potential benefit to the patient.

G. Hologic's Awareness of Minerva

25. I am aware that on January 6, 2010, Hologic and Minerva entered into a Non-Disclosure Agreement (NDA) that reflected Minerva's interest at the time of "evaluating a potential business collaboration." Ex. 3. The NDA was signed by Mr. Rohan Hastie, Hologic's Senior Director of Business Development. As a start-up, Minerva was naturally interested in a meaningful investment or acquisition.

26. On April 15, 2011, Mr. Russell Layton, Hologic's Senior Director of Strategy & Emerging Technologies – GYN Surgical, reached out to our CEO, Dave Clapper, introduced himself and asked to meet at "the upcoming ACOG meeting." Ex. 17.

27. On or about May 13, 2011, Mr. Layton paid a visit to Minerva. Ex. 20 (redacted Minerva visitors register showing R. Layton entry).

* * *

35. Minerva's EAS (originally code named Aurora) operates in a completely different way than the NovaSure. *Id*. at MSI00001661. It uses a fluid-tight sealed silicone membrane and a patented Plasma Formation Array technology to thermally heat the tissue gently and effectively. *Id*. at MSI00001662, MSI0001669-1672. During our presentation to Ms. Petrovic we showed her a video of our Minerva PFA operating to heat egg white. Ex. 15 (PFA in eggwhite) at MSI00001673. Different from the NovaSure, the Minerva EAS relies on, and benefits from, the accumulation of a moisture layer during ablation at the tissue/membrane interface. Minerva's external sealed silicone membrane heats this liquid layer, which effectively gets into the nooks and crannies of the uterine tissue, and so facilitates a more complete and gentle ablation.

36. Here I refer to recent side-by-side video of the Minerva device (left) and NovaSure (right) operating in a beaker of egg white for demonstration purposes. The video shows how because the NovaSure delivers significantly more RF power to the applicator head, it consequently also generates significantly more steam (see significantly more bubbling for the NovaSure) than Minerva's lower power device. Ex. 25.

37. As an added benefit, Minerva's external sealed silicone membrane is smooth. This smooth surface, in conjunction with the moisture layer, make it much easier to pull the Minerva's PFA away from the tissue (*i.e*., retract it) following the procedure, since the smooth membrane generally does not stick to the tissue. In contrast, the NovaSure uses RF energy to electrically heat the external metallic mesh. The NovaSure transports moisture away from the tissue as I described, and so during the ablation, the hot metal-

lic mesh is drawn into direct contact with the tissue. As a consequence, when the ablation is done, tissue will often stick to the surface of the mesh, complicating its retraction and withdrawal of the device from the patient. Ex. 16; Ex. 10 at MSI00004480 ("Device Removal is Difficult").

* * *

I declare under penalty of perjury of the laws of the State of California and the United States that each of the above statements is true and correct. Executed on March 7, 2016, in Redwood City, California.

/s/ Evgueni Skalnyi
Evgueni Skalnyi, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 15-1031-SLR

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

MEMORANDUM ORDER

At Wilmington this 2nd day of June, 2016, having reviewed the papers filed in connection with plaintiffs' motion for preliminary injunction, and having heard oral argument on same;

IT IS ORDERED that plaintiffs' motion (D.I. 9) is denied, for the reasons that follow:

1. **Procedural background.** On November 6, 2015, plaintiffs Hologic, Inc. and Cytyc Surgical Products, LLC ("Cytyc") (collectively plaintiffs or "Hologic") filed a complaint alleging infringement of U.S. Patent Nos. 6,872, 183 ("the '183 patent"),[1] 8,998,898 ("the '898 patent"),[2] and 9,095,348 ("the

[1] Titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004 and issued March 29, 2005.

[2] Titled "Moisture Transport System for Contact Electrocoagulation," filed May 15, 2014 and issued April 7, 2015.

'348 patent"),[3] against defendant Minerva Surgical Inc. ("Minerva").[4] (D.I. 1) On February 5, 2016, Hologic filed a second amended complaint pursuant to a stipulation, adding allegations relating to U.S. Patent No. 9,247,989 ("the '989 patent").[5], [6] (D.I. 69, 70) On February 29, 2016, the court denied Minerva's motion to transfer and strike Hologic's preliminary injunction motion.[7] (D.I. 82) On March 4, 2016, Minerva answered the complaint and counterclaimed. (D.I. 83) On March 28, 2016, Hologic answered the counterclaims. (D.I. 106)

2. Hologic, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Marlborough, Massachusetts. It provides women's health care services including diagnostics, screening, and imaging, as well as medical intervention and treatment. Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business in Marlborough, Massachusetts.

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[3] Titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013 and issued August 4, 2015.

[4] On January 6, 2016, Minerva filed a motion to dismiss, which was subsequently withdrawn. (D.I. 43, 62) On January 25, 2016, Hologic filed an amended complaint. (D.I. 59)

[5] Titled "Moisture Transport System for Contact Electrocoagulation," filed March 2, 2015 and issued February 2, 2016.

[6] For purposes of the preliminary injunction motion practice, the parties agreed not to rely on the '898 patent. (D.I. 42 at 2) Neither party refers to the '989 patent. (D.I. 11, 86)

[7] The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Cytyc is engaged in designing, developing, and selling medical devices for the treatment of excessive or abnormal endometrial bleeding. Cytyc is a wholly-owned subsidiary of Hologic, Inc. (D.I. 70 at ¶¶ 2-4) Minerva is a corporation formed in 2008. It is organized and existing under the laws of the State of Delaware with a principal place of business in Redwood City, California. Minerva has developed and brought to market a new technology for the treatment of abnormal uterine bleeding. (D.I. 83 at ¶¶ 119, 124)

3. **Factual background.** "Menorrhagia" is abnormally heavy menstrual bleeding in amount or duration. One treatment for this condition is an "endometrial ablation," wherein lining of the uterus is destroyed. In the early 1990s, physicians had to visually inspect the uterus for perforations using a hysteroscope, as such perforations can allow steam or hot fluids generated during ablation to escape the uterus and cause serious injury to nearby organs. Furthermore, small perforations were hard to detect. To perform the ablation, physicians used instruments such as an electrified metal ball or wire loop to burn tissue away inside the uterus. The procedures were lengthy and carried serious risks. (D.I. 11 at 2-3)

4. NovaCept Corporation ("NovaCept") under the direction of Csaba Truckai ("Truckai") and his design team developed the NovaSure system ("NovaSure") in the late-1990s. The U.S. Food and Drug Administration ("FDA") approved NovaSure in 2001. (D.I. 70 at ¶ 10; D.I. 86 at 2) In May 2004, Cytyc Corporation, a leading provider of diagnostic and therapeutic treatments for women, acquired NovaCept for $325 million. In 2007, Hologic, Inc. acquired Cytyc Corporation. (D.I. 11 at 5; D.I. 86 at 2)

5. Prior to an ablation procedure, NovaSure uses computerized monitoring to detect perforations in the uterus, by applying CO_2 gas to the uterus and measuring whether there is any flow of gas out of the uterus. NovaSure employs an application head with a triangular shape designed to conform to the shape of the uterus, which ablates the endometrial lining throughout the cavity in two minutes or less. The procedure is considerably shorter, less expensive, and more convenient for the patient. NovaSure also provides a "moisture transport" function with a vacuum used to remove steam and moisture from the cavity during energy delivery. (D.I. 11 at 3-5)

6. In July 2015, Minerva obtained FDA approval for a new device for the treatment of menorrhagia ("Minerva EAS"), developed by Truckai and his design team. Minerva has hired and trained a sales force to begin selling Minerva EAS to physicians. (D.I. 86 at 4)

7. **Standard.** "The decision to grant or deny . . . injunctive relief is an act of equitable discretion by the district court." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006); *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006). The grant of such relief is considered an "extraordinary remedy" that should be granted only in "limited circumstances." *See Kos Pharma., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). A party seeking preliminary injunction relief must demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) the public interest favors such relief. *See, e.g.*, *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d

1253, 1259 (Fed. Cir. 2012); *Abbott Labs v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008). "If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if relief is not granted—are absent, an injunction cannot issue." *Antares Pharma., Inc. v. Medac Pharma., Inc.*, 55 F. Supp. 3d 526, 529 (D. Del. 2014) (citing *McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994)).

8. At the preliminary injunction stage of a case, the movant "'must demonstrate that . . . at least one of [the] allegedly infringed claims will . . . likely withstand the validity challenges presented by the accused infringer.'" *Abbott Labs.*, 452 F.3d at 1335 (citation omitted).

> As to the burden regarding invalidity allegations, "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." . . . In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity at trial.

Id. (citation omitted).

9. Even if a movant demonstrates a likelihood of success on the merits, there is no presumption of irreparable harm. *See, e.g.*, *eBay*, 547 U.S. at 393. To

establish irreparable harm, the movant must "clearly establish[ ] that monetary damages could not suffice." *Id.* at 1348. Moreover, Federal Circuit precedent requires a showing of some causal nexus between the alleged infringement and the alleged harm. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.").

10. **The '348 patent.** The '348 patent is directed to "an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ." It uses "an electrode array," which "includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon." To use the apparatus, "the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." ('348 patent, 2:34-45) The specification describes two exemplary embodiments. The first embodiment describes an ablation device comprised generally of three major components – RF applicator head, main body, and handle. (*Id.* at 4:55-58) The applicator head includes an array of electrodes formed on the surface of an electrode carrying means. (*Id.* at 4:58-61) "The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array." Aspects of the two "exemplary embodiments and their methods of operation may be

combined without departing from the scope of the present invention." (*Id.* at 11:50-58) Claim 1 recites:

> A device for treating a uterus comprising:
>
> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
>
> an **applicator head** coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a **deflecting mechanism** including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured

> so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and
>
> an **indicator mechanism** operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

(*Id.* at 19:9-42) (emphasis added)

11. **Likelihood of success on the merits – infringement.** As to claim 1, Minerva argues that Minerva EAS lacks the claimed "deflecting mechanism," "applicator head," and "indicator mechanism." (D.I. 86 at 14, 16, 18) For each of these limitations, Hologic asserts that the claim language is clear and readily understood, therefore, expert testimony or extrinsic evidence is unnecessary for claim construction. (D.I. 11 at 9) Minerva offers specific constructions for the disputed limitations, which the court discusses below.

12. **"Deflecting mechanism."** In the description of the second embodiment, the '348 specification explains that the "[a]pplicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue." ('348 patent, 12:5-8) The "[d]eflecting mechanism 102b and its deployment structure is enclosed within electrode array 102a." (*Id.* at 13:8-9) The deflecting mechanism is preferably configured such that the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use." (*Id.* at 14:1-3) "The deflecting mechanism formed by the flexures 124, 136, and [transverse] ribbon 138 forms the array into

the substantially triangular shape shown in [figure] 23, which is particularly adaptable to most uterine shapes." (*Id.* at 14:21-24) The specification further explains that "[e]ach internal flexure 136 is connected at its distal end to one of the flexures 124 and a transverse ribbon 138 extends between the distal portions of the internal flexures 136." The transverse ribbon "is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in [figure] 23 and such that when in a compressed condition it is folded along the plurality of creases 140 that extend along its length." (*Id.* at 13:60-54) Dependent claim 2 recites "[t]he device of claim 1 further comprising a transverse ribbon coupled to a distal end of the first and second external flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state." (*Id.* at 19:43-46)

13. Hologic identifies the flexures in the applicator head of Minerva EAS as satisfying the "deflecting mechanism" limitation. (D.I. 11 at 11) Minerva's proposed construction[8] is repetitive in the context of the actual claim language, which recites and describes "flexures." Minerva's non-infringement argument relies on this construction, i.e., that Minerva EAS does not use or need a transverse ribbon to conform to the shape of the uterus. (D.I. 86 at 16) Neither claim 1 nor the specification requires that the transverse ribbon be part of the "deflecting mechanism." Given the language of the specification

[8] "A deployment structure enclosed within the electrode array of the applicator head that consists of outer flexures, inner flexures and a transverse ribbon that extends between the flexures." (D.I. 86 at 14)

and claims, Hologic has made a prima facia showing that Minerva EAS satisfies this limitation.

14. **"Applicator head."** The summary of the invention explains that the "electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon . . . and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." ('348 patent, 2:37-45) In the first embodiment, the applicator head "includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode carrying means 12." (*Id.* at 4:58-61) The electrode carrying means is "preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture . . . . Alternatively, the electrode carrying means may be formed of a metallized fabric." (*Id.* at 5:52-61) The main body of the ablation device includes a shaft with a "suction/insufflation tube" extending through it. (*Id.* at 4:57, 5:3-4) The suction/insufflation tube is "coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38. For example, suction may be applied to the fluid port 38 using a suction/insufflation unit 40." (*Id.* at 8:20-25) The water vapor from the uterine cavity passes "thorough the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38." (*Id.* at 8:27-29) The specification also describes the operation of the ablation device, including that "[m]oisture removal from the ablation site may be further facilitated by the application of

suction to the shaft 10 using the suction/insufflation unit 40." (*Id.* at 10:65-67) The specification explains that "liquid build-up at the ablation site is detrimental" and that moisture is shunted away from the ablation site, which prevents liquid build-up. (*Id.* at 11:1-13) Suction may also be used to help draw the organ tissue towards the electrode carrying means and into better contact with the electrodes. (*Id.* at 9:1-6) The specification provides that "additional components inside" the electrode carrying means may "add structural integrity to [it] when it is deployed within the body." For example, "a pair of inflatable balloons may be arranged inside the electrode carrying means," which balloons can then be inflated after insertion of the apparatus into the organ. (*Id.* at 8:47-67)

15. In the second embodiment, the applicator head "includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue." (*Id.* at 12:5-8) The array "is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material."(*Id.* at 12:10-12) The embodiment describes using a vacuum source, which causes "application of suction" to help "draw uterine tissue into contact with the array." (*Id.* at 18:40-43) The embodiment describes a "plurality of longitudinally spaced apertures" formed in each flexure that allow moisture to pass through the flexures and be drawn into a hypotube 120 using a vacuum source. (*Id.* at 13:13-18) In describing the operation of the second embodiment, the specification explains that as moisture is released from the tissue, the vacuum source helps to draw moisture from the uterine cavity into the hypotube. (*Id.* at 18:44-52)

16. Hologic identifies Minerva EAS' applicator head as meeting this limitation. Minerva argues that Minerva EAS "uses a fluid-tight, sealed silicone outer membrane, which is not permeable to moisture;" instead, the formation of a moisture layer is beneficial to the operation of Minerva EAS. (D.I. 86 at 17) Minerva's proposed construction[9] seeks to narrow the claim language to the second embodiment and adds limitations which are not required by the specification or claim language. Specifically, the use of suction to draw in moisture is not required. As to permeability, the specification contemplates that the electrode array be made of a material that is permeable to moisture. Hologic's reference to the balloon example in the first embodiment is not helpful, as the context of that example is to provide stability to the electrode carrying means.[10] Minerva

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[9] "A working end having a permeable external electrode array into which moisture is drawn using suction." (D.I. 86 at 16)

[10] The specification describes the shortcomings of the prior art methods including that "water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow" and "the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths." ('348 patent, 2:9-19) The specification also states that "liquid build-up at the ablation site is detrimental." (*Id.* at 11:1-13) The court concludes that such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by Minerva. *Cf. Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1025 (Fed. Cir. 2015) (citing *Inpro II Licensing, S.A.R.L. v. T-Mobile USA Inc.*, 450 F.3d 1350, 1354-55 (Fed. Cir. 2006)) ("Likewise, we have used disclaimer to limit a claim element to a feature of the preferred embodiment when the specification described that feature as a 'very important feature . . . in an aspect of the present invention,' and disparaged alternatives to that feature.").

has raised a substantial question regarding whether Minerva EAS satisfies this limitation.

17. **"Indicator mechanism."** In the second exemplary embodiment, the specification describes a "measurement device," "for easily measuring the uterine width and for displaying the measured width on a gauge." A dial face "includes calibration markings corresponding to an appropriate range of uterine widths." The uterine width is

> preferably input into an RF generator system and used by the system to calculate an appropriate ablation power . . . . Alternately, the width as measured by the apparatus of the invention . . . may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

('348 patent, 14:32-67)

18. Hologic identifies Minerva EAS' red and green areas and the lines of 3, 4, and 5 dots as meeting the "indicator mechanism" limitation. (D.I. 11 at 11) Minerva EAS' manufacturing specification refers to the indicator on the handpiece as a "width indicator." (D.I. 115, ex. 10 at 6.2.12, 6.3.13) The dot scale on the width indicator shows widths of about 3, 4, and 5 cm, respectively, via the rows of 3, 4, and 5 dots. (D.I. 115, ex. 8 at 42412; ex.10 at 6.3.13) Minerva's medical director testified that Minerva's clinical data excludes women with uteri that are smaller than 2.5 cm and the width indicator on Minerva EAS' handpiece indicates when a patient's uterus is smaller than 2.5 cm. (D.I. 115, ex. 7 at 164:22-165:5) Minerva's proposed construction limiting "indicator mechanism" to "a mechanism configured to indicate a measurement of width in units" is incorrect. (D.I. 86

at 18-19) Hologic has made a prima facia showing that Minerva EAS satisfies this limitation.

19. **Likelihood of success on the merits – invalidity.** Minerva argues that there is no enabling disclosure for a plasma formation array with a non-permeable and fluid-tight silicone membrane. Minerva's expert opines that it would require undue experimentation for a person of ordinary skill in the art to arrive at Minerva EAS' design, particularly as the specification teaches away from the thermal techniques used by Minerva EAS. (D.I. 88 at ¶¶ 175-76) Hologic argues that Minerva's claim construction is incorrect and that the specification describes non-permeable arrays in figure 20. (D.I. 114 at 8-9) As discussed above regarding the construction of "applicator head," the specification contemplates membrane permeability. Minerva has raised a substantial question of invalidity.[11]

20. **The '183 patent.** The '183 patent is directed to "a system and method for detecting perforations in a body cavity." The system delivers a fluid (either liquid or gas) "into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted." In the preferred form of the system, the perforation detection functionality is provided with

[11] Minerva points out that it has filed an IPR petition challenging the validity of the '348 patent and asserted a defense based on obviousness-type double-patenting to establish that the correct expiration date for the '348 patent is April 12, 2016. (D.I. 86 at 20) Such assertions carry little weight in the present analysis.

an RF ablation system. ('183 patent, 1:49-62) Claim 9 recites:

> A method of detecting a perforation in a uterus, comprising the steps of:
>
> passing an inflation medium into the uterus;
>
> monitoring for the presence of a perforation in the uterus using a **pressure sensor**;
>
> if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and
>
> if a perforation is detected during the monitoring step, preventing ablation of the uterus.

(*Id.* at 8:39-48) (emphasis added) Dependent claim 13 limits claim 9 reciting, "wherein the inflation medium is introduced using the ablation device." (*Id.* at 60-61)

21. **"Pressure sensor."** The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." ('183 patent, 2:36-44) The pressure sensor "monitors pressure in the pressure signal line . . . and delivers the signal to the microprocessor." (*Id.* at 5:23-25) The specification explains that during testing "[w]hen the pressure at gauge 84 rises and remains above 50 mmHg for 4 seconds, the test has passed." (*Id.* at 6:44-46)

22. Hologic has identified Minerva EAS' flow meter as meeting the "pressure sensor" limitation. Minerva argues that the flow meter does not measure pressure (differential or otherwise) to operate and its output is not a pressure measurement.[12] (D.I. 86 at 8-11) Minerva EAS' operator manual describes a "uterine integrity test" aimed at detecting perforations. (D.I. 12, ex. 11 at 9, 33) Minerva's expert, Dr. Tucker, testified, "[a]s the pressure goes down, the flow rate goes up. As the pressure goes up, the flow rate goes down." (D.I. 115, ex. 2 at 64:17-20) The design documents for Minerva EAS state that "if the uterine cavity and the system is perforation free, gas used to insufflate the uterine cavity will stop flowing once the gas pressure in the uterine cavity matches the supply pressure." (D.I. 87, ex. 82 at 2337) The court concludes that the evidence supports a prima facia showing of infringement.[13, 14]

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[12] Minerva criticizes William Churchill's ("Churchill") analysis under the doctrine of equivalents, arguing that Churchill's chart is conclusory and only analyzes a hypothetical "standard flow meter." Minerva's expert, Dr. Tucker, testified that Minerva EAS uses a "standard flow meter." (D.I. 115, ex. 2 at 33:20-25)

[13] Minerva's argument that Minerva EAS embodies Minerva's patent (U.S. Patent No. 8,343,078) and uses a flow meter is relevant but not dispositive of the issue at bar. *National Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1192 (Fed. Cir. 1996) ("The fact of separate patentability is relevant and entitled to due weight.").

[14] The court declines to analyze Minerva's prosecution history estoppel argument at length. (D.I. 86 at 12-13) During the prosecution history of a related application, the PTO rejected a claim with the limitation "monitoring a pressure within the body cavity for a predetermined amount of time," because the prior art disclosed "a system and method for . . . monitoring pressure within the body cavity for a predetermined amount of

23. **Likelihood of success on the merits – invalidity.** Dr. Tucker opines that a person of ordinary skill would need to engage in undue experimentation to use a flow meter to perform the claimed "monitoring" function. Therefore, Minerva argues that the disclosure lacks enablement. (D.I. 88 at ¶¶ 116-19) Hologic disputes this conclusion, arguing that Dr. Tucker agreed that a person of ordinary skill could measure flow rate and pressure. (D.I. 115, ex. 2 at 64:24-66:2; ex. 6) According to Hologic, known methods may be used to quantify the relationship between flow and pressure in the uterus. (D.I. 114 at 5) Based on the evidence presented by the parties, the court concludes that Minerva has not raised a substantial question of invalidity in this regard.

24. **Likelihood – conclusion.** As to the '348 patent, Minerva has advanced plausible non-infringement and invalidity arguments with respect to the "applicator head" limitation. As to the '183 patent, Hologic has put forth a prima facia showing of infringement and Minerva has not raised a substantial question of invalidity with its lack of

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time." The claim was ultimately allowed after amending other elements of the claim to overcome the rejection. In the application which issued as the '183 patent, the patentee included a claim with the same limitation. Such claim was then cancelled and a new claim was added reciting "monitoring for the presence of a perforation in the uterus using a pressure sensor." Contrary to Minerva's argument, the court discerns no clear and unmistakable surrender of all equivalents to a "pressure sensor." Cf. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (A presumption of prosecution history estoppel is established by showing that the patentee made a narrowing amendment and that "the reason for that amendment was a substantial one relating to patentability.").

enablement argument. For these reasons, Hologic has met its burden of showing likelihood of success on the merits with respect to the '183 patent only.

25. **Irreparable harm.** Minerva's correspondence introducing Minerva EAS to physicians states that it was designed to address "difficulties with 'seating' the array, obtaining accurate width measurement, obtaining a secure cervical seal, and most importantly disappointing clinical outcomes." (D.I. 12, ex. 13) Minerva argues that "physicians are trying [Minerva EAS] because it is new technology and [has] new features." In support, Minerva offers a physician's declaration stating that he tried Minerva EAS because "it might offer . . . patients significant benefits over and above the NovaSure System." (D.I. 86 at 24; D.I. 90 at ¶ 12) Despite this argument, the description of Minerva EAS in Minerva's correspondence suffices to show "some causal nexus" between the infringing product (and certain patented features) and the alleged harm. *See Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 642 (Fed. Cir. 2015) ("[T]he district court should have considered whether there is "some connection" between the patented features and the demand for Samsung's products. That is, the district court should have required Apple to show that the patented features impact consumers' decisions to purchase the accused devices.) (citations omitted); *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("If the patented feature does not drive the demand for the product, sales would be lost even if the offending feature were absent from the accused product. Thus, a likelihood of irreparable harm cannot be shown if sales would be lost regardless of the infringing conduct.").

26. **Reputation and goodwill.** Hologic offers the declarations of its sales territory manager (D.I. 14), chief operating officer (D.I. 16), and vice president of surgical sales (D.I. 19), to argue that Minerva is representing that it "invented the NovaSure system and now developed [Minerva EAS] as a 'new NovaSure' that addresses the 'weaknesses' of the existing NovaSure." Hologic alleges that these representations are confusing customers. (D.I. 11 at 16) The evidence presented in support includes an email from a Minerva sales representative that reads "the group who developed [Minerva EAS] is the same exact group who created and developed the NovaSure procedure 14 years ago." (D.I. 12, ex. 13) A template letter from a sales representative sent to potential customers reads "Minerva was developed by the same person that invented NovaSure over 15 years ago. It is an evolutionary product that addresses many unmet needs . . . ." (D.I. 116, ex. 37 at 4746; ex. 38 at 34963; ex. 39 at 34896) The same representative tells customers that Minerva EAS was developed by the same person who invented NovaSure, as it establishes credibility and is true. (D.I. 115, ex. 27 at 106:17-107:5) Minerva responds that such correspondence is not misleading as it "displays Minerva's logos, "Minerva Surgical, Inc." signature blocks, @minervasurgical.com email addresses, and other distinctive features." (D.I. 15, exs. 13-14) Minerva offers the declaration of its vice president for sales and marketing, stating that Minerva's sales staff is instructed to compare Minerva EAS to all endometrial ablation products, not just to NovaSure. (D.I. 91 at ¶¶ 8-12) According to the record at bar, the specific representations in the evidence are true, that is, Truckai and his research group were the original inventors of NovaSure at NovaCept and have now

invented Minerva EAS at Minerva. Hologic has not offered specific evidence that Minerva is representing itself as currently affiliated with Hologic or NovaSure.[15] Therefore, this fact weighs in favor of Minerva.

27. **Lost sales and price erosion.** Hologic's declarant states that several of Hologic's large customers have requested price discounts on future long-term agreements as a result of Minerva's entry into the market. (D.I. 11 at 17; D.I. 19 at ¶¶ 11-13) Minerva's sales correspondence to physicians acknowledges such discounts,[16] while encouraging physicians to try Minerva EAS. (D.I. 116, ex. 31 at 19844, ex. 32 at 2669, ex. 33 at 19444, ex. 34 at 5386) According to Hologic, it will be nearly impossible to calculate the lost downstream sales to the customers that Minerva lures away. This is due to the differing types of sales and contracts that are possible, i.e., purchasing the controller and then purchasing the disposables or receiving the controller for free and purchasing the disposables at a higher price. Hologic also asserts that price erosion will be difficult to calculate as prices are negotiated on a per customer basis. Hologic concludes that money damages will not compensate for the damage to its brand and reputation as the pioneer in endometrial ablation.[17] (D.I. 11 at 17-18) Minerva counters that Hologic has

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[15] Hologic's declarant agreed at deposition that if Minerva sales staff "followed their script," such communications would not be misleading. (D.I. 87, ex. 35 at 139-40)

[16] For example, stating that Hologic is providing free NovaSure controllers and offering discounts in an effort to retain its customers and compete with Minerva EAS.

[17] Hologic has not offered to license the patents-in-suit to a third party.

discounted NovaSure in recent years to compete with other treatments and enter into multi-product agreements, which offer discounts across product lines, but result in higher volume and increased revenue. (D.I. 86 at 22-23)

28. Sales of NovaSure were flat in the fiscal year ending in September 2012 and declined in the fiscal years ending in September 2013-2015. In its SEC filings, Hologic attributed the sales decline to lower cost alternatives and market forces.[18] (D.I. 87, exs. 30-33) There was an increase in NovaSure sales in fiscal year 2016, with Hologic reporting a $3.2 million revenue increase in NovaSure sales for the first quarter of fiscal year 2016 (October to December 2015) and NovaSure sales of $55.2 million (an increase of 8.1%) for the second quarter (January to March 2016).[19] (D.I. 87, ex. 34; D.I. 124, ex. 1) In sum, Hologic carefully tracks the average price and sales volume of NovaSure for each of its accounts, weakening Hologic's argument that money damages would not suffice. (D.I. 87, ex. 35 at 13, 164-65) The court concludes that this factor is neutral.

29. **Other factors.** Hologic points out that it is in direct competition with Minerva and Minerva is focusing its efforts on Hologic's existing high volume customers. The record demonstrates that the parties compete with each other as well as with other

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[18] Minerva also points to Hologic's unsuccessful launch of NovaSure 4.0, which failed in early 2015, as a factor in the fluctuating price for NovaSure. (D.I. 86 at 22)

[19] According to Hologic, the most recent increase was the result of the unexpected recall and exit from the market of Johnson & Johnson's competing "ThermaChoice" product, which left a sudden, large demand that both Hologic and Minerva have sought to satisfy. (D.I. 125)

endometrial ablation products (e.g., Johnson & Johnson's ThermaChoice and Boston Scientific's HTA), lower cost treatments and procedures (e.g., over-the-counter hormone pills and intrauterine devices ("IUDs")), and traditional surgical procedures (e.g., hysterectomies and dilation/curettage). (D.I. 86 at 21-22; D.I. 87, exs. 30-33) This factor is neutral.

30. Hologic asserts that Minerva's willful copying shows irreparable harm. Hologic bases its copying allegations on the similarity in key product features of NovaSure and Minerva EAS (D.I. 11 at 9),[20] as well as the allegations of misrepresentation by Minerva discussed above in relation to reputation and goodwill. Minerva denies the copying allegations, representing that it uses a different technology,[21] a single return electrode on the exterior of a plasma forming array to ablate tissue. The plasma forming array has a thin silicone membrane allowing thermal ablation. Minerva's technology is the result of seven years of research, with FDA trials and patent applications. Moreover, visual dissimilarity and branding dispel confusion. (D.I. 86 at 5-7) This factor is neutral.

31. Minerva argues that Hologic unreasonably delayed bringing the lawsuit and present motion, which should weigh against a finding of irreparable harm. Hologic had some notice and knowledge of Minerva EAS as it investigated acquiring Minerva in 2011-12 with information provided pursuant to a

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[20] At least two physicians noted the similarities in the technology. (D.I. 115, ex. 8; D.I. 116, ex. 66 at 32624)

[21] Minerva represented to the FDA that Minerva EAS was "almost dead identical to NovaSure except [that it uses] plasma energy (RF)." (D.I. 116, ex. 67)

non-disclosure agreement. Hologic avers that the FDA approved Minerva EAS in August 2015, Hologic obtained a device in September 2015 to analyze whether there was a good faith basis for infringement, filed the present lawsuit in November 2015, and moved for the present injunction in December 2015. While Hologic's initial investigation may not have been focused on infringement, it does appear that the timing of its lawsuit and motion strategically coincides with the launch and starting sales of Minerva EAS. *Hybridtech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988) ("A period of delay is but one circumstance that the district court must consider in the context of the totality of the circumstances."). This factor is neutral.

32. **Irreparable harm – conclusion.** Based on the arguments presented above, most of the factors presented to the court are neutral. Therefore, Hologic has not demonstrated irreparable harm due to competition from Minerva.

33. **Balance of harms.** This factor is largely neutral. Hologic alleges that it has invested heavily in making NovaSure the leading treatment in endometrial ablation through additional clinical work and research, training and education for physicians, and training a salesforce. The court has determined that Hologic may be adequately compensated by money damages. Although Minerva took a calculated risk launching its product, an injunction precluding Minerva from selling its only product would cause it great harm.

34. **Public interest.** This factor is largely neutral. Although the public has an interest in protecting valid patents, patients have an interest in new developments in medical technologies. Each party

holds up data and argument regarding "safety and efficacy" for the court to consider in the present analysis. The FDA has approved Minerva EAS and any analysis of the safety and efficacy thereof is outside the purview of the court in the present context.

35. **Conclusion.** For the foregoing reasons, Hologic's motion for preliminary injunction (D.I. 9) is denied.

/s/ Sue L. Robinson
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 15-1031-SLR

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

MEMORANDUM ORDER

At Wilmington this 24th day of April, 2017, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. 6,872, 183 ("the '183 patent"), 9,095,348 ("the '348 patent"), 8,998,898 ("the '898 patent"), and 9,247,989 ("the '989 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"Pressure sensor:"**[1] "A device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal." Plaintiffs had proposed "a device that senses pressure," and defendant had proposed "a device whose input detects a force per unit area and that outputs a corresponding electrical signal." (D.I. 155 at

[1] Found in '183 patent, claims 1 and 9.

1) At oral argument, the court articulated the above construction, and the parties agreed with the exception of the "or indirectly" component. (D.I. 225 at 37:25-38:27) Defendant argued that the pressure sensor must measure the force per unit area "directly." (D.I. 199 at 3) Plaintiffs contended that indirect forms of measuring pressure are equally valid. (D.I. 201 at 7; D.I. 202 at ¶ 19) The specification describes a "pressure sensing system" that monitors the presence of a perforation in the uterus:

> Pressure sensing system 24 monitors the pressure within the body cavity BC while fluid/gas is being (or after it has been) delivered to the body cavity, and detects whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ.

('183 patent, 2:37-43; *see also id.*, abstract; 1:53-57; 5:18-37) Nothing in the specification requires the pressure sensor to measure pressure "directly" so long as the pressure sensor can "detect whether elevated pressure can be maintained [in the uterus] . . . over a predetermined period of time."[2]

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[2] Defendant presented extensive extrinsic evidence to support its argument that a pressure sensor must measure pressure directly and cannot measure pressure indirectly. Dr. Robert Tucker ("Dr. Tucker") opined that a person having ordinary skill in the art "would know that pressure can be measured in millimeters of mercury ('mmHg') . . . that refers to a size of a column of elemental mercury that can be supported by the force exerted by a given amount of pressure." (D.I. 200 at ¶ 23) The data sheet for the SenSym amplified SCX series sensor (identified as an example embodiment in the '183 patent)

2. **"Monitoring:"**[3] "Monitoring."[4]

3. **"Applicator head:"**[5] "A distal end portion of an ablation device that applies energy to the uterine tissue."[6] Claim 1 of the '348 patent recites:

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measures pressure by its effect on "an integrated circuit sensor element." (D.I. 172, ex. P at A-3) In these examples, the measurement is based upon the effect of pressure on a physical component (e.g., a column of mercury or a semiconductor) and known physical relationships (gravity, temperature, atmospheric pressure, and so forth). Dr. Gregory T. Martin ("Dr. Martin") explained that "[i]n fact, commercially available pressure sensors almost always measure pressure by some indirect means." (D.I. 202 at ¶ 19) Based upon this record, defendant's proposed construction (limiting the term to "direct" measurement) would exclude commercially-available pressure sensors from the scope of the term "pressure sensor."

[3] Found in '183 patent, claims 1, 5-7, 9, and 11.

[4] The court adopts plaintiffs' proposal. Defendant proposed "measuring a condition in a system" but did not identify any support in the specification for such a construction. (D.I. 199 at 13-14)

[5] Found in '348 patent, claims 1, 5, 8, and 12.

[6] The court adopts plaintiffs' proposal. Defendant proposed "an applicator having a permeable or absorbent tissue contacting surface into which moisture is drawn." (D.I. 155 at 2) The specification describes the shortcomings of the prior art methods including that "water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow" and "the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths." ('348 patent, 2:9-19) The specification also states that "liquid build-up at the ablation site is detrimental." (*Id.* at 11:1-13) Defendant presented extensive argument for reading these limitations from the specification into the claims. (D.I. 199 at 15-24) However, "[t]he court concludes that such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by [defendant]." (D.I. 127 at 11, n.10)

> A device for treating a uterus comprising:
>
> . . . .
>
> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus; . . .

('348 patent, 19:9-21) The '348 patent describes an embodiment with reference to figures 1 and 2 in which

> an ablation device . . . is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. . . . The RF applicator head 2 includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode carrying means 12.

('348 patent, 4:55-61; figures 1 & 2, item 2) In another embodiment,

> applicator head 102 extends from the distal end of a length of tubing 108 which is slidably disposed within the sheath 104. Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.

('348 patent, 12:3-8; figure 23, item 102)

4. **"An energy applicator:"**[7] "An applicator of an ablation device that delivers energy to the uterine tissue." The court adopts plaintiffs' construction for the same reasons as "an applicator head," above.

5. **"A working end:"**[8] "A distal end portion of an ablation device that applies energy to the uterine tissue." Claim 1 of the '898 patent recites an "ablation device comprising a tubular member coupled to a working end, the working end comprising a first electrode and a second electrode" ('898 patent, 19:31-33) The specification describes that "[a]n ablation device is provided which has an electrode array carried by an elongate tubular member" and "[d]uring use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue." ('898 patent, 2:38-44)

6. **"An indicator mechanism:"**[9] "A mechanism configured to indicate a dimension."[10] Claim 1 of the '348 patent recites "an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus." ('348 patent, 19:40-42) With reference to the second embodiment of the '348 patent, the "ablation device . . . includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge 146." ('348 patent, 14:33-

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[7] Found in '989 patent, claims 1, 11, 13-15.

[8] Found in '898 patent, claims 1-5, 14, and 22.

[9] Found in '348 patent, claim 1.

[10] The court adopts plaintiffs' proposal. Defendant proposed "a measuring device used to display a value in units of measure." (D.I. 155 at 2) Nothing in the specification suggests that applicant intended to limit "an indicator mechanism" to devices that solely display uterine widths in "units of measure."

36; *see also id.*, 15:55-56) Figure 32b shows that "dial face 158 includes calibration markings corresponding to an appropriate range of uterine widths." (*Id.*, 14:47-49; figure 32b, item 158)

7. **"One or more electrodes:"**[11] "One or more electrical conductors." The "applicator head" in claim 1 of the '348 patent "includ[es] one or more electrodes for ablating endometrial lining tissue of the uterus."[12, 13] ('348 patent, 19:19-21) **Extrinsic evidence:** a technical dictionary definition of "electrode" is "[a]n electrical conductor through which an electric current enters or leaves a medium." (D.I. 161, ex. 21 at 3)

8. **"At least one electrode:"**[14] "One or more electrical conductors."[15]

9. **"First and second electrodes:"**[16] "First and second electrical conductors."[17]

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[11] Found in '348 patent, claim 1.

[12] The court adopts plaintiffs' proposal. Defendant proposed that "each electrode has a polarity and contacts the tissue surface during ablation." (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having a polarity or to contacting the tissue surface during ablation.

[13] Claim 1 of the '348 patent is a system claim. The construction proposed by defendant constrains the manner in which the claim limitation ("at least one electrode") is used (in contact with the tissue surface). Such a construction would make the claim indefinite. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (holding a claim invalid for claiming a system and a method for using that system).

[14] Found in '989 patent, claim 2.

[15] *See supra* note 12.

[16] Found in '898 patent, claims 1, 8, 14, and 22

10. **"Sack:"**[18] "An electrode-carrying member having a bag-like shape." Claim 3 recites "[t]he method of claim 2 wherein the working end includes a sack comprised of a non-conductive material." ('898 patent, 19:47-48) With respect to the first embodiment, the specification states that "[e]lectrode carrying means 12 is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression." ('898 patent, 5:58-63) Defendant argued that the additional limitations (i.e., permeability, moisture absorption, and compression) from this embodiment should be included in the construction. (D.I. 199 at 21-22; D.I. 155 at 2) Applicant chose to explicitly limit the "sack" in claim 2 to "non-conductive material," but nothing in the intrinsic record suggests that applicant intended the term to implicitly include the limitations proposed by defendant.

11. **"Balloon:"**[19] "An inflatable member." The specification discloses an embodiment in which "a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in figure 20." ('898 patent, 9:3-5) Defendant proposed "an inflatable member inside the energy

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[17] The court adopts plaintiffs' proposal. Defendant proposed that "the first and second electrodes are of opposite polarity and each contacts the tissue surface during ablation." (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having opposite polarities or to contacting the tissue surface during ablation.

[18] Found in '898 patent, claim 3.

[19] Found in '898 patent, claims 4, 5; '989 patent, claims 5, 6, 17, 18.

applicator/working end and not in contact with the tissue." (D.I. 155 at 2-3) Defendant presented attorney argument that "[t]he 'balloon' itself does not contact the tissue. Rather, a purpose of balloon 52 is to be inflated and thereby hold the external electrodes 'in contact with the interior surface of the organ to be ablated.'" (D.I. 199 at 31 (citing '898 patent, 8:59-60)) While the disclosed embodiment includes the balloon inside the "electrode carrying means 12," which is the "energy applicator" or "working end" in the relevant patents, nothing in the specification suggests this is the only possible embodiment. Moreover, a balloon located inside the "stretchable metallized fabric mesh" of the "RF Applicator Head" of the second embodiment may contact uterine tissue. Therefore, the court adopts plaintiffs' proposal.

12. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

/s/ Sue L. Robinson
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR-SRF

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs and Counterdefendants,

v.

MINERVA SURGICAL, INC.,

Defendant and Counterclaimant.

JURY TRIAL DEMANDED

DECLARATION OF CSABA TRUCKAI

TABLE OF CONTENTS

I, Csaba Truckai, declare as follows:

1. I am the current President and Chief Executive Officer of Corinth MedTech, Inc., in Cupertino, California. I am also a current Director of Minerva Surgical, Inc. in Redwood City, California – a company I founded in 2008. I am also a named inventor on over 140 U.S. patents and approximately the same number of pending patent applications.

2. I have founded and served as an executive in a number of medical device companies over the past 20 years. One such company was Novacept, Inc., which I co-founded in 1993 and which was located in Palo Alto, California, at the time. A copy of my Curriculum Vitae is at MSI00299668-669 (Ref. 1).[1]

3. I served as President of Novacept until March 2000. Novacept marketed a product called the NovaSure endometrial ablation system, which my team and I designed and developed. The NovaSure system consists of two primary components: a non-disposable Radio Frequency ("RF") Controller and a disposable handpiece. By the late 1990's, our development efforts led to the final design of our NovaSure endometrial ablation system that received FDA approval in 2001, and which Novacept then began to sell commercially.

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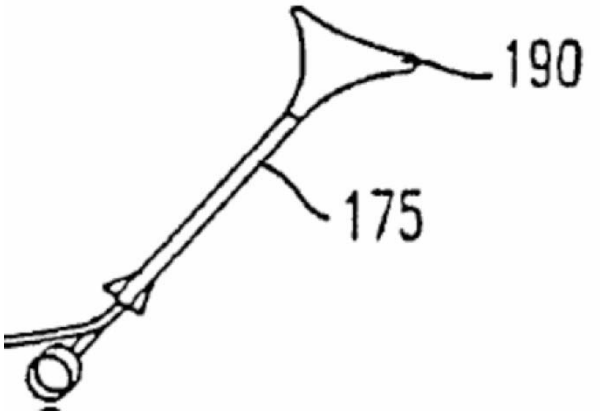
[1] Throughout my report I refer to certain references. I have not attached these references directly to this declaration, although I do expressly incorporate them by reference. Each reference I cite in this document has been produced in this litigation, and I include a chart at the end of my declaration identifying the Bates number for each.

I. THE '348 AND '989 ("MOISTURE TRANSPORT") PATENTS

A. The Moisture Transport Prototypes and Patents

4. In the mid-to-late 1990s, my co-inventors and I designed various prototypes for use in the ablation of human tissue, including prototypes for an endometrial ablation device. In that same timeframe we filed a number of applications with the U.S. Patent & Trademark Office (Patent Office) based on these prototypes. Our initial prototype for use in the uterus consisted of three basic components, as was common at the time for such surgical devices, including: (i) a handle; (ii) a slender tube used for inserting the device into the uterus via the cervical canal; and (iii) an applicator head (i.e., the distal end of the device) designed to be inserted in a compressed state, and then expanded into an uncompressed state that approximates the roughly triangular shape of the uterus. See e.g., U.S. Patent No. 5,443,470, (Ref. 2), Figs. 1 and 12, disclosed in the "Background" section of the '348 and '989 patents (i.e., the "Asserted Moisture Transport patents"):



5. Our initial prototype for what evolved into the NovaSure handpiece included the following features:

- The exterior, tissue-contacting portion (which I will refer to as the "external electrode array") of the applicator head was composed of a liquid-permeable mesh designed to draw the tissue in close contact with the bipolar electrodes to deliver RF energy to the targeted tissue, and to permit moisture and steam generated as a result of the RF tissue heating process to be drawn into the interior of the applicator head for subsequent evacuation through a central tube;
- Our prototype was Radio Frequency-only (i.e., an RF-only) ablation device with the electrodes (both positive and negative) located on the exterior surface of the external electrode array because they had to contact the uterine tissue in order to deliver energy and ablate the tissue;
- We experimented with various patterns of positive and negative electrodes on the surface of the array, but in all cases the electrodes were placed on the exterior surface of the array so that they could contact the tissue;
- By the mid-1990s, we understood that it was detrimental to the operation of our prototype device to allow a layer of moisture to build up between the electrodes and the uterine tissue for all the reasons we described and disclosed in our patents and provisional identified below; and
- We also tried prototypes where the distal end was made of an absorbent material (e.g., open celled sponge) in order to draw moisture into

the distal end and away from the electrode/ tissue interface.

6. On April 12, 1996, based on our initial prototyping efforts, my co-inventor, Dr. David Auth, and I filed U.S. Patent Application No. 08/632,516. The '516 Application later issued as U.S. Patent No. 5,769,880 (the '880 patent). Ref. 3. The '880 patent generally describes an endometrial ablation device with a tissue-contacting surface composed of either a permeable mesh or an absorbent material (e.g., open cell sponge). By April 12, 1996, Dr. Auth and I had realized that it was very important to the effective operation of our device to actively or passively draw the moisture into the external electrode array and away from the uterine tissue during ablation. This initial prototype, on which the disclosures in the '880 patent were based, had a syringe-like handle with finger grips.

7. Over approximately the next two years, we continued to refine our initial prototype. In that timeframe we came to realize that it was not just important, but critical, to the effective operation of our device to use suction to actively draw the moisture into the applicator head using a permeable mesh array and away from the uterine tissue during ablation. Basically, our experiments showed that the failure to prevent the formation of a moisture layer between our surface electrodes and the tissue would result in an uncontrolled and uneven depth of ablation. We concluded that the failure to draw the moisture away from the tissue and into the array during the ablation was highly detrimental to the operation of our prototype of the NovaSure for at least several reasons, the details of which we disclosed to the Patent Office in the

specification of our patents as well as our May 8, 1998 provisional application.

8. To summarize, the presence of a moisture layer would: (i) divert the current from flowing through the target tissue; (ii) cause undesirable thermal ablation by heating the moisture layer in an uncontrolled way; (iii) interfere with how the system controlled the depth of ablation; and (iv) draw more current than necessary to perform the ablation. I believed at the time (as I still do today) that it is highly undesirable to use more electric current than necessary inside the human body.

9. In the late 1990's, I considered the mechanism I describe above and used in our prototype for drawing moisture into the applicator head and away from the tissue to be the "moisture transport" system central to the proper operation of all of our endometrial ablation prototypes, as reflected by the title and content of our various filed applications including the May 8, 1998 provisional I describe below.

10. Due to the importance of our moisture transport system, our refined prototype used only a permeable metallic mesh external electrode array (we no longer considered a merely absorbent external electrode array to be an option). Our refined design also included the addition of holes along the outer flexures (to better draw moisture across and into the mesh array), as well as the non-optional use of suction to actively draw moisture away from the tissue so that it could be evacuated through a tube inside the array (illustrated as item 122 of Fig. 23 below). We illustrated and described our moisture transport system—including the permeable mesh and its advantages over prior art non-permeable RF balloons and other

thermal techniques—in our various applications; see e.g., Ref. 4, Figs. 23, 26A showing the mesh, and Fig. 28 showing the moisture being drawn into the array:

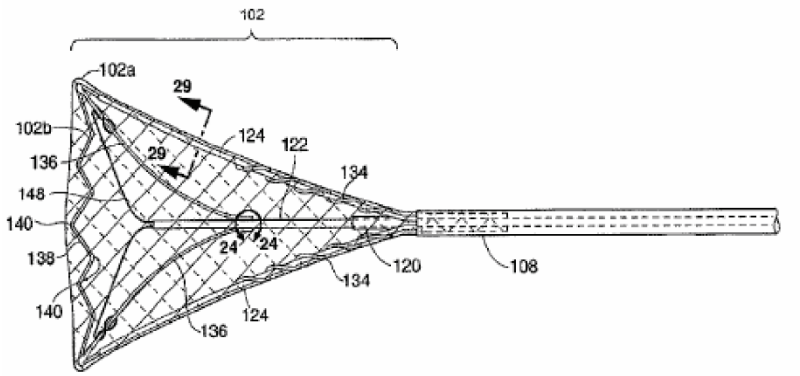


FIG. 23

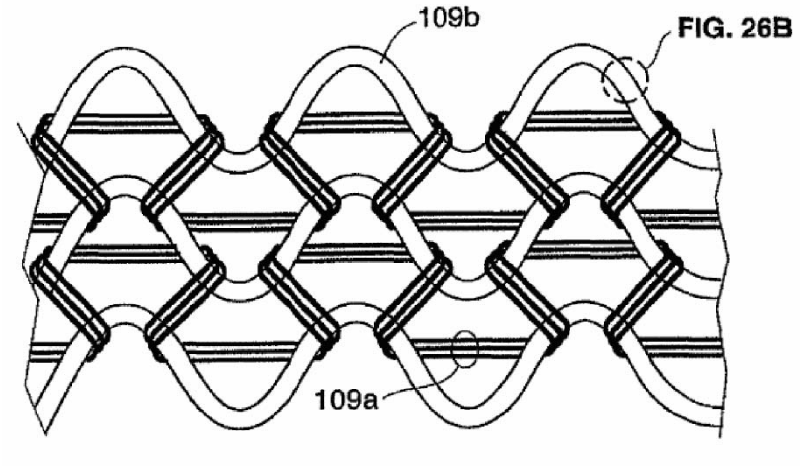


FIG. 26A

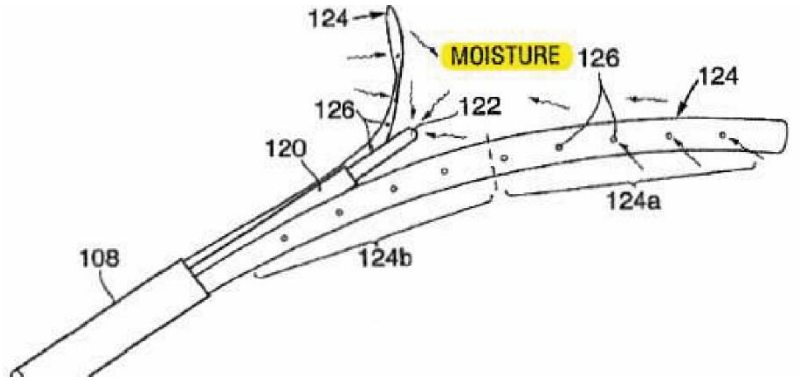
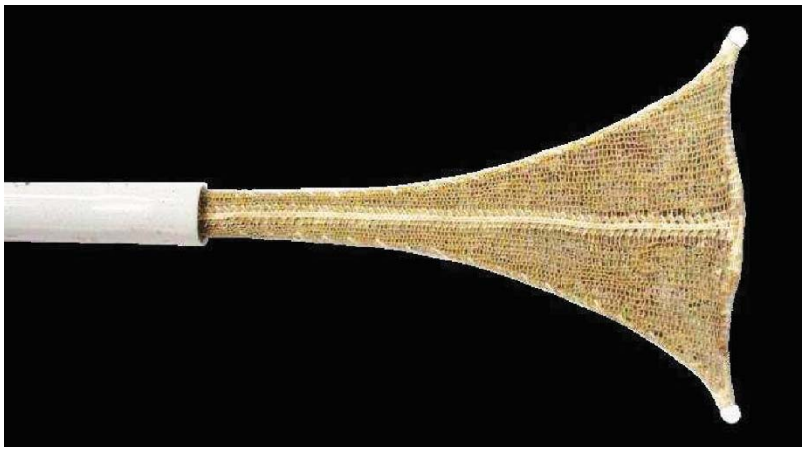


FIG. 28

11. On May 8, 1998, based on our refined prototype, Novacept filed U.S. Provisional Application No. 60/084,791 (the "Moisture Transport" or "MT" Provisional), titled, "Moisture Transport System for Contact Electrocoagulation." Ref. 5. The MT Provisional lists me and four other individuals (Russel Sampson, Stephanie Squarcia, Alfonzo Ramirez, and Estela Hilario) as inventors/applicants.

12. On June 23, 1998, shortly after filing the MT Provisional, Novacept filed U.S. Application No. 09/103,072. The '072 application issued as U.S. Patent No. 6,813,520 (the '520 patent). The '520 patent is titled, "Method For Ablating And/Or Coagulating Tissue Using Moisture Transport," and lists me and four other individuals (Russel Sampson, Stephanie Squarcia, Alfonzo Ramirez, and Estela Hilario) as inventors. Ref. 4. The '520 patent is a continuation-in-part of the '880 and claims the benefit of U.S. Provisional Application No. 60/084,791. Our refined prototype, on which the disclosures in the MT Provisional and '072 application were based, used a handle with distal and proximal grips pivotally attached at a pivot point, rather than the earlier syringe-like handle.

13. The above filings with the Patent Office basically reflect the evolution of our endometrial ablation prototypes during the mid-to-late 1990s. The final design of the distal end of our NovaSure endometrial ablation system, which received FDA approval in 2001, included a permeable metallic mesh external electrode array as I show below:



14. Prior to May 8, 1998 (or even June 23, 1998), the exterior, tissue-contacting surface of the applicator head of our endometrial ablation system prototypes (on which we based our patent applications) were made of a fluid-permeable mesh or an absorbent material (I recall trying gray open cell urethane packaging foam). At no time prior to May 8, 1998 (or even June 23, 1998) did our endometrial ablation system prototypes use a non-permeable external membrane (e.g., a balloon), as that would have frustrated the entire purpose of our moisture transport system.

15. At no time prior to May 8, 1998 (or even June 23, 1998) do I recall any of our prototypes for an endometrial ablation device including an internal electrode designed and/or intended to remain out of contact with the tissue.

16. At no time prior to May 8, 1998 (or even June 23, 1998) do I recall any of our prototypes for an endometrial ablation device including any sort of plasma formation capability; nor do I recall my co-inventors and I even discussing how to use plasma to ablate uterine tissue, much less how to use an internal electrode to ignite an inert noble gas to create an ionized plasma for ablating uterine tissue through a non-permeable, thin-walled, sealed silicone membrane.

17. Novacept was sold to Cytyc Corporation in 2004. In 2007, Cytyc Corp. was in turn acquired by Hologic, Inc. Over time, the various owners filed a series of applications all stemming directly from the '520 patent, all listing me as a named inventor. I show the sequence over time of filings that led to the Asserted Moisture Transport patents (highlighted in yellow) in the chart below. See also Ref. 37 (MT Family Genealogy):

FILING DATE	APPLICATION	ISSUED AS
May 8, 1998	MT Provisional Application No. 60/084,791	N/A
June 23, 1998	U.S. Application No. 09/103,072	U.S. Patent No. 6,813,520
October 6, 2004	U.S. Application No. 10/959,771	U.S. Patent No. 7,604,633
October 19, 2009	U.S. Application No. 12/581,506	U.S. Patent No. 8,506,563
August 8, 2013	U.S. Application No. 13/962,178	U.S. Patent No. 9,095,348

May 15, 2014	U.S. Application No. 14/278,741	U.S. Patent No. 8,998,898
March 2, 2015	U.S. Application No. 14/635,957	U.S. Patent No. 9,247,989

18. On August 8, 2013—five years after Minerva was formed—Hologic filed the first of two applications describing the moisture transport system now being asserted against Minerva in this lawsuit. Specifically, Hologic filed U.S. Patent Application No. 13/962,178, which issued as U.S. Patent No. 9,095,348. Ref. 6.

19. On March 2, 2015—seven years after Minerva was formed—Hologic filed U.S. Patent Application No. 14/635,957. In November 2015, Hologic sued Minerva in this case. About three months later, the '957 Application issued on February 2, 2016, as U.S. Patent No. 9,247,989 (the '989 patent). Ref. 7 (highlighted in yellow in chart above). The '989 patent is the second of the two moisture transport system patents now being asserted against Minerva in this lawsuit.

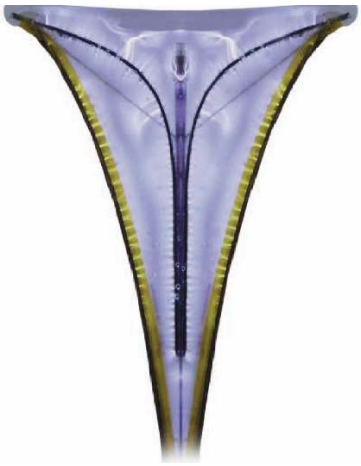
20. Collectively, I will refer to the '348 and '989 patents as the "Asserted Moisture Transport" or "Asserted MT" patents. I am aware from my experience with patents that because the Asserted MT patents are direct descendants of the '520 patent, they share a common specification with the '520 patent (i.e., basically only the claims of each patent starting with the '520 are different). See Ref. 37.

B. Minerva's Accused Plasma Formation Array (PFA) Technology

21. Minerva began the development of a plasma-formation array in 2008—ten years after we filed our May 8, 1998 Moisture Transport Provisional.

22. Minerva refers to the distal end (i.e., the portion that a surgeon deploys inside the uterus to ablate the tissue) of its disposable handpiece as a Plasma Formation Array ("PFA"). Unlike the NovaSure, the exterior of Minerva's PFA consists of a smooth, non-permeable (i.e., fluid tight) sealed silicone membrane carefully selected for its conductive properties. The non-permeable sealed silicone membrane is designed to enclose an inert Argon gas that circulates within the membrane. Both prior to and during an ablation procedure, the Argon flows into, circulates, and flows out of the membrane via a lumen in the center of the Minerva device.

23. In the center of the PFA is, among other things, an electrode of one polarity. That inner electrode is enclosed within the non-permeable, sealed silicone membrane, and thus does not contact the uterine tissue. The inner electrode is used to ignite the Argon gas and thereby create a plasma, which in turn, creates filaments that strike the inner surface of the membrane. See e.g., Ref. 33 (Video of PFA in action; filaments appear as blue microbolts); see illustration below:



24. As may be obvious, Minerva's PFA simply would not work if the external membrane was permeable for a number of reasons, including that the Argon gas would escape into the uterine cavity, would not circulate properly within the membrane, and would be contaminated by moisture and thus could not be ignited. Basically, if perforated, our PFA would not function as intended. In fact, as I discuss below with respect to our UIT, our Minerva system would alert the physician if a perforation in the PFA were detected.

25. The second "return" electrode of the opposite polarity consists of two conductive strips located on the exterior narrower sides of the PFA.

26. The Minerva PFA relies on three mechanisms to ablate the uterine tissue: two thermal and one RF. The primary mechanism used by Minerva's PFA is thermal. During the ablation procedure, plasma filaments strike the interior surface of the silicone membrane (i.e., not the tissue). This action creates heat along the interior surface of the membrane. That heat is conducted through the membrane to its exterior surface, where the heated exterior surface of the PFA starts ablating the adjacent uterine tissue.

27. The second mechanism used by Minerva's PFA is also thermal. The uterine cavity is naturally moist to some extent. However, as uterine tissue begins to ablate, the cells of the endometrium begin to desiccate and exude moisture (essentially saline). By design, because Minerva's PFA has a sealed, non-permeable outer membrane, it purposely retains the moisture in the uterine cavity as that moisture builds up during the ablation. Because the exterior surface of the PFA heats up, it also heats the retained moisture.

28. Importantly, uterine tissue is not flat. It is composed of millions of tiny folds of tissue. The moisture heated by Minerva's PFA flows into those folds during the ablation, resulting in a more gentle and even ablation of the uterine tissue than we were able to achieve with the NovaSure design. Minerva's PFA thus relies on the presence of the heated moisture within the cavity as a second thermal mechanism to ablate the tissue. Minerva's handpiece purposefully does not use the older moisture transport mechanism to draw fluid/steam away from the uterine tissue and into the interior of the PFA.

29. The third mechanism used by Minerva's PFA is a radio frequency (RF) mechanism. A relatively small amount of RF current (as compared to the NovaSure) flows between the single internal electrode and the second external "return" electrode on the exterior of the PFA. During the ablation, a small amount of RF current travels through the plasma, the non-permeable silicone membrane and the uterine tissue.

30. Also, as I describe further below, the results of our electro-chemical testing during the R&D phase of our PFA design revealed a surprising and non-predictable benefit due to the physics of how the plasma energy and RF current would very rapidly seek out the low-impedance paths through the target tissue (the "scanning" mechanism I describe in more detail below). Due to the unique and novel physics of Minerva's design, the plasma energy and small amount of RF current effectively seeks out the less ablated tissue, thereby facilitating a more gentle and even ablation while using roughly a quarter of the power used by the NovaSure endometrial ablation system.

C. The Development of Minerva's Accused Device

31. Starting in approximately March/April 2008, my team and I began exploring an initial concept as a first step in a multi-year process that eventually culminated in the current Minerva PFA design, which the FDA approved for use in July 2015. This initial concept was to make a lab bench prototype that would ablate tissue with ionized gas in fulguration mode using a prototype bi-polar Argon gas coagulator with a porous ceramic membrane, as well as an isolation/insulating gas (other than Argon) to control the plasma distribution contacting the tissue. Due to the thickness and variable pore size of the ceramic membrane, the results of this initial electro-chemical testing were not predictable.

32. This initial non-routine development and testing extended through approximately August 2008. In approximately August 2008, my team and I also conducted an important experiment. This experiment took place when, using a sheet of silicone (a "dielectric") instead of the ceramic membrane as part of a fulguration chamber, we accidentally discovered during a fulguration experiment that the sheet of silicone had created a barrier discharge plasma-forming prototype that could ablate/coagulate tissue.

33. In approximately August 2008 (shortly before Minerva was formed) and based on the accidental discovery noted above, my team and I redirected our efforts and modified our initial concept into an alternative design. This alternative design became a lab bench prototype that would ablate tissue through heating of an impermeable dielectric layer (the silicone sheet). The distal end of the prototype had to create one or more a fluid-tight interior chambers to

hold the gas, which allowed formation of a barrier discharge plasma. The use of this dielectric layer allowed for a complete physical separation between the tissue and the plasma. Moreover, we learned that the use of a smooth silicone membrane had another advantage in comparison to older technologies such as the NovaSure disposable handpiece; namely, our smooth silicone membrane prevented tissue charring and/or sticking following the ablation (e.g., Ref. 8 at p.3).

34. Our modified design used two impermeable members that formed the two poles of the bipolar system. The two impermeable members were separated by a third chamber that contained isolation/insulating gas (other than Argon) to prevent arcing. We faced numerous choices, setbacks and challenges in coming up with a final distal configuration for our PFA. For example, we experimented with different thicknesses of the membrane, including having a membrane with regions of different thicknesses in order to alter the applied energy and depth of ablation in each region (e.g., Ref. 8 at p.3). We experimented with membranes having different dielectric constants to affect the depth of ablation; as well as a membrane with a gradient in dielectric constant to thereby provide a gradient in depth of energy delivered to the tissue (e.g., Ref. 8 at p.4). We experimented with having multiple interior chambers for the gas, each with its own interior electrode (e.g., Ref. 8, Fig. 5). We also experimented with different shapes and configurations of the membrane (e.g., Ref. 8, Figures). At the time, for a particular configuration, for example, we thought that it was preferable to use a dielectric constant of at least 5 (e.g., Ref. 8 at p.4).

35. Our experimentation continued through approximately February 2009. The progression of our prototyping efforts from roughly late summer 2008 through early 2009 is reflected in the following sequence of videos and photos taken on or about this time period by our team. See Exs. 17 to 22.

36. Starting in approximately March 2009, Minerva conducted further experiments demonstrated on the bench that showed that the design concept for the PFA could be further reduced to a single impermeable (dielectric) membrane with a small non-heating electrode because of the unique electrical characteristics of the ionized Argon gas. An important breakthrough is that we came to understand what we called the "scanning" mechanism we had developed and how it led to a more controlled, rapid and even ablation. Simply put, the high intensity electric field that we were able to successfully generate inside the membrane would convert the gas into a plasma. In turn, this allowed plasma filaments (seen as tiny blue-glowing filaments in our videos) to form within the membrane. Those filaments appear to "jump" or "scan" around the interior surface of the membrane in a random fashion.

37. As I previously noted, as uterine tissue begins to ablate, the cells of the endometrium begin to desiccate. As they desiccate, they also become more resistive to current flow (i.e., the impedance through that tissue increases). Due to the novel physics of our PFA technology, the filaments are, in effect, drawn to the path of least resistance though the tissue—which happens to be the tissue that requires further ablation. As the target tissue becomes ablated, its impedance increases and eventually reaches a threshold where the amount of power being delivered is then

reduced resulting in the desired depth of ablation. E.g., Ref. 9 at 10:63 – 12:59 and Figs. 9A to 10.

38. In the course of our experimentation, we also discovered that the external "return" electrode can have a relatively small surface area and yet not be subject to significant heating. Ref. 9 at 12:47-50. We also continued to experiment with different shapes including variants with sharp tips for ablation of a tumor, electrosurgical jaw structures, as well as more balloon-like membranes for cardiac and other uses. One prototype had more of a cylindrical shape, while another had several needle-like ablation elements (e.g., Ref. 9 (Figures)). We also continued to experiment with different thicknesses of dielectric. Toward the end of our experimentation with this revised design, the tissue-contacting electrode of a single polarity was moved to the exterior surface of the impermeable membrane (e.g., Ref. 9 at 10:34-37).

39. The progression of our prototyping efforts from roughly March 2009 through summer 2009 is reflected in the following sequence of videos and photos taken by our team during roughly this time period. See Exs. 23 to 32.

40. With this work completed, the next phase of the project was to evolve the same concept into a design that was incorporated into an actual medical device circa June 2009. The design of our disposable handpiece continued to evolve until Q1 2011, in advance of Minerva's clinical trials. We continued to make a few modifications to the overall system culminating in our final Generation 2 design, which is FDA approved.

41. To summarize, my team and I had to perform numerous experiments during the development

phases described above to eventually arrive at the final, working design of Minerva's PFA. As my filings with the Patent Office show, our experiments during these phases helped us determine, for example:

- The novel use of plasma to ablate tissue (e.g., Ref. 9 at 7:51-67; Ref. 11 at 5:10-49);
- How my novel "scanning" mechanism worked (e.g., Ref. 9 at 10:63 – 12:59 and Figs. 9A to 10);
- The right degree of plasma ionization needed to create a "cold" plasma and how that degree of ionization is related to temperature (e.g., Ref. 9 at 8:36-9:3);
- The need to create a sealed, fluid-tight interior chamber to hold the gas (e.g., Ref. 11 at 7:59-63);
- What type of gas to use within the fluid-tight interior chambers of our various prototype configurations (e.g., Ref. 9 at 3:41-43 ("Argon or another noble gas)) and later in our PFA (e.g., Ref. 11 at 2:54-59 ("Argon"));
- The preference for the inert gas to have a gas inflow channel and gas outflow channel so that the gas can circulate and continuously flow within the interior chamber to maintain plasma quality (e.g., Ref. 9 at 13:51-54; Ref. 11 at 2:8-12, 2:43-46, 3:25-28 and 6:10-11);
- The appropriate shape, composition and thickness of the sealed thin-walled membrane (e.g., Ref. 11 at 2:28-31, 3:5-11, 4:12-13, 6:21-28 and 11:17-19);
- How to ignite and control the gas within the fluid-tight interior chamber (e.g., Ref. 9 at 7:25-39);

- How to capacitively couple the ionized plasma to the tissue via a thin-walled dielectric membrane to deliver RF current to ablate the target tissue (e.g., Ref. 9 at 10:63-11:8);
- How the use of a smooth silicone membrane had the advantage that it prevented tissue charring and/or sticking to the device following the ablation (e.g., Ref. 8 at p.3);
- The design of the internal electrode (e.g., Ref. 9 at 3:10-14);
- The importance of the first polarity internal electrode having exposure to all regions of the neutral gas and plasma within the interior chamber (e.g., Ref. 11 at 6:42-47);
- The interaction and relative placement of the internal electrode versus the external electrode (e.g., Ref. 11 at 3:56-60, 8:35-39 and 8:48-51);
- A preferred volume for the interior chamber (e.g., Ref. 11 at 3:38-39);
- The need for a low pressure in the interior chamber (e.g., Ref. 11 at 6:36-42 and 11:21-25);
- A practical degree of ionization for the membrane to provide feedback control of applied power (e.g., Ref. 9 at 8:36-47);
- A workable flow rate of the non-conductive gas (e.g., Ref. 11 at 3:64-65 and 11:15 16);
- The proper level of RF power and frequency needed to be delivered to the PFA over the duration of the procedure (e.g., Ref. 11 at 11:27-31);

- The ranges of voltage, current and frequency delivered by the RF power source to the PFA (e.g., Ref. 11 at 2:47-53);
- The dependence of the threshold voltage at which the neutral gas becomes conductive on various factors (e.g., Ref. 9 at 7:15-22 and 13:13-21);
- An appropriate delay between the initial flow of Argon gas and when the controller begins delivery of RF power to allow circulatory gas flow (e.g., Ref. 9 at 13:21-24);
- Achievable ablation depths (e.g., Ref. 9 at 6:57-62 and Ref. 11 at 11:2-5);
- How to control the depth of the ablation (e.g., Ref. 9 at 16:44-48);
- An appropriate time interval for the ablation (e.g., Ref. 11 at 11:31-34);
- The method (i.e., steps) of operation (e.g., Ref. 11 at 4:56-64, 9:50-57 and Fig. 8C); and
- The design of the subsystem and its feedback control systems for controlling operating parameters of the plasma (e.g., Ref. 11 at 9:14-48).

D. Minerva's PFA Patents

42. On October 21, 2008, I filed U.S. Provisional Application No. 61/196,870 (the "PFA Provisional"), titled, "System for Tissue Ablation." Ref. 8. I am the named inventor on the PFA Provisional. The PFA Provisional teaches the outcome and conclusions from some of my early experimentation on the use of plasma formation technology to ablate tissue.

43. U.S. Patent Application Nos. 12/541,043 and 12/541,050 were filed on August 13, 2009. These two

patent applications later issued as U.S. Patent Nos. 8,372,068 (the "PFA I" patent) and 8,382,753 (the "PFA II" patent), respectively. Exs. 9 and 10. I am the named inventor on these two Minerva patents.

44. My PFA I and PFA II patents reflect my progress and illustrate some of my various prototypical configurations for electrosurgical devices and methods for rapid, controlled ablation of tissue using a current to ignite a plasma contained within a thin dielectric layer. As the figures of the PFA I and II patents show, at the time I was contemplating a variety of different medical applications for the plasma-based ablation technology, including a device configured for ablation of various structures within the human body, such as a tumor, pulmonary veins, and cardiac applications, and of course endometrial ablation, among others.

45. U.S. Patent Application No. 12/605,546 was filed on October 26, 2009. This application later issued as U.S. Patent No. 8,500,732 (the "PFA III" patent). Ref. 11. Mr. Akos Toth and I are the named inventors on this patent. I will refer to the PFA I, II and III patents collectively as the "PFA Patents." The specifications of Minerva's PFA patents (which also incorporate the PFA Provisional by reference) collectively disclose a significant amount of detail about the findings my team and I made during our extensive experiments with materials, configurations, and other design elements in the time spent developing what is now Minerva's PFA.

46. I disclosed information about what we learned from our many experiments to the U.S Patent & Trademark Office in my PFA Provisional and PFA patents since it has been my understanding that an inventor should disclose sufficient information and

detail regarding his or her research, design and experimentation to allow others in the field to make and use the invention without having to "reinvent the wheel," so to speak.

47. As can be seen in the "References Cited" sections of each of the three PFA Patents, during prosecution Minerva (or Hermes) routinely disclosed to the Examiner numerous patents including at least several direct ancestors to the Asserted MT patents (e.g., the 5,769,880 and 6,813,520 Truckai patents, Exs. 3 and 4). See Ref. 9 at MSI00014351; Ref. 10 at MSI00013677 and Ref. 11 at MSI00013186. For example, Minerva disclosed these older '880 and '520 Moisture Transport System patents to the Examiner as prior art from the mid-to-late 1990s so that the Patent Office would be fully aware of the nature of these older prior art technologies, of which I was also an inventor, in deciding whether to grant Minerva its own patents covering its new plasma formation array technology.

48. After these prior art disclosures, the Patent Office granted all three of Minerva's PFA Patents. Therefore, since at least February 2013 when the Patent Office granted Minerva's PFA I and PFA II patents, it continues to be my belief that the U.S. Patent Office considered Minerva's PFA Patents to cover inventions that were not previously patented; in other words, that described and claimed new and useful inventions that were patentably distinct from the invention of the older Moisture Transport System patents.

II. THE '183 PATENT VERSUS MINERVA'S UTERINE INTEGRITY TEST (UIT)

A. The Pressure Sensor Family and Prototypes

49. On November 10, 1999, my co-inventors and I filed U.S. Provisional Application No. 60/164,482. Ref. 12. One year later, on November 10, 2000, my co-inventors and I filed U.S. Application No. 09/710,102, which later issued as U.S. Patent No. 6,554,780 (the '780 patent). Ref. 13. The '780 patent and its direct descendants—all continuations—are shown in the chart of Ref. 38 (Pressure Sensor Family Genealogy).

50. On May 24, 2004, my co-inventors and I filed U.S. Application No. 10/852,648, which issued on March 29, 2005, as U.S. Patent No. 6,872,183 (the '183 patent). Ref. 14. The '183 patent lists me and three other individuals (Russel Sampson, Mike O'Hara and Dean Miller) as inventors. Hologic has asserted the '183 patent against Minerva in this lawsuit. The '183

* * *

diagram of Fig. 14 shows the step "CO2 Flow Check," representing the step of using our flow meter to check the flow rate of CO2 gas to check for perforations in the uterus.

76. Our UIT patents disclose information we learned from our many experiments. I believe the information we disclose in our UIT patents includes information others in the field would need to make and use our flow meter-based solution for determining if there is a perforation in the uterus without having to go through the same experimental process.

77. During prosecution of Minerva's UIT patents, Minerva disclosed to the Examiner both the'183 patent currently being asserted against Minerva, as

well as its parent, the '780 patent. Ref. 15 at MSI00003817 and Ref. 16 at MSI00003843.

78. Although fully aware of the asserted '183 patent, the Examiner issued both Minerva's UIT I and UIT II patents and allowed Minerva to claim how to determine the presence of a perforation in the uterus using only a flow sensor. See e.g., Ref. 15 at MSI00003841 ("a flow sensor for measuring a flow rate") and Ref. 16 at MSI00003867 ("measuring a flow rate"). Minerva's UIT flow sensor only detects a flow rate (and not a pressure, whether directly or indirectly) and sends a signal that corresponds to a value of flow rate in units of ccm—and not a pressure (i.e., force per unit area)—to the microprocessor.

III. SUPPORTING REFERENCES

REF	DESCRIPTION/NOTES	PROD.#
1	Csaba's CV	MSI00299668 - MSI00299669
2	U.S. Patent No. 5,443,470	MSI00171139 – MSI00171159
3	U.S. Patent No. 5,769,880	MSI00013616 – MSI00013639
4	U.S. Patent No. 8,813,520	MSI00013582 – MSI00013615
5	U.S. Provisional Application No. 60/084,791 (the "Moisture Transport" or "MT" Provisional)	MSI00014937 – MSI00015029
6	U.S. Patent No. 9,095,348	MSI00013489 – MSI00013520

7	U.S. Patent No. 9,247,989	MSI00144513 – MSI00144544
8	U.S. Provisional Application No. 61/196,870 (the "PFA Provisional")	MSI00012999 – MSI00013019
9	U.S. Patent No. 8,372,068 (the "PFA I" patent)	MSI00014350 – MSI00014407
10	U.S. Patent No. 8,382,753 (the "PFA II" patent)	MSI00013676 – MSI00013733
11	U.S. Patent No. 8,500,732 (the "PFA III" patent)	MSI00013185 – MSI00013207
12	U.S. Provisional Application No. 60/164,482	MSI00013850 – MSI00013855
13	U.S. Patent No. 6,554,780	MSI00013084 – MSI00013096
14	U.S. Patent No. 6,872,183	MSI00012930 – MSI00012940
15	U.S. Patent No. 8,394,037 (UIT I)	MSI00003816 – MSI00003841
16	U.S. Patent No. 8,343,078 (UIT II)	MSI00003842 – MSI00003867
17	.wmv video file	MSI00148499
18	.wmv video file	MSI00148495
19	Picture	MSI00148494
20	.mov video file	MSI00148498
21	.mpg video file	MSI00148485
22	Picture	MSI00148493

23	.mov video file	MSI00148496
24	Picture	MSI00148487
25	.wmv video file	MSI00148492
26	Picture	MSI00148491
27	.mov video file	MSI00148484
28	Picture	MSI00148486
29	.wmv video file	MSI00148488
30	Picture	MSI00148489
31	.mov video file	MSI00148497
32	.wmv video file	MSI00148490
33	Minerva's video of its PFA (filaments appear as blue micro-bolts)	MSI00002327
34	May 7, 2009 Draft Function Requirements Specification Minerva Controller	MSI00297528-MSI00297535
35	June 8, 2009 Draft Product Specifications – Minerva Controller	MSI00297538-MSI00297551
36	MNmain.c	MSI_SC_0056 - MSI_SC_0074
37	Moisture Transport Family Genealogy	MSI00299670
38	Pressure Sensor Family Genealogy	MSI00299671

IV. CONCLUDING STATEMENTS

79. I declare under penalty of perjury of the laws of the State of California and the United States that each of the above statements is true and correct. Executed on June 29, 2017, in Redwood City, California.

/s/ Csaba Truckai
Csaba Truckai

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-SLR-SRF

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs and Counterdefendants,

v.

MINERVA SURGICAL, INC.,

Defendant and Counterclaimant.

JURY TRIAL DEMANDED

EXPERT REPORT OF DR. ROBERT TUCKER, M.D., Ph.D. REGARDING INVALIDITY OF U.S. PATENT NOS. 6,872,183, 9,095,348 AND 9,247,989

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* * *

32. As a separate basis for invalidity, in my opinion each asserted claim of each of the patents-in-suit is invalid in that each fails to meet the enablement requirement, as I explain in detail below.

VII. CLAIM CONSTRUCTION

33. I understand the Court has issued a Claim Construction Order in this case, dated April 24, 2017, which sets forth the construction of certain disputed claim terms, as well as claim terms that have been agreed to by the parties. I attach a chart of these

constructions as Exhibit C. I have assumed and applied these claim constructions for purposes of my report. I reserve the right to supplement this report if necessary or appropriate, including but not limited to, in the event that any of the claim constructions change.

VIII. GENERAL BACKGROUND

34. Millions of women suffer from a condition known as menorrhagia, which is excessive and/or prolonged bleeding of the endometrium (i.e., the interior lining of the uterus). This condition is often accompanied by debilitating cramping and other discomfort, and in extreme cases can lead to fatalities due to anemia/blood loss. Over the decades, there have been numerous medical instruments designed to alleviate this condition by "ablating" the tissue cells of the endometrium.

35. Ablation of tissue is basically the process of destroying the tissue cells. Ablation can be accomplished using various techniques and forms of energy, including radio frequency ("RF") energy that basically runs an electric current through the tissue, and thermal ablation that employs heated liquid to destroy the cells. Ablation of tissue is not unique to the uterus, but has long been used to treat tissue in many parts, organs and body cavities of the human body. Some examples include the gallbladder, heart (e.g., to treat atrial fibrillation) and tumors. The ablation devices at issue are used for endometrial ablation.

IX. THE MOISTURE TRANSPORT SYSTEM PATENTS[3]

A. The "Applicator Head" and "Energy Applicator" Terms of the Asserted Moisture Transport Claims

36. Claim 1 of the '348 patent is the sole asserted independent claim. The remaining asserted claims all depend directly or indirectly on Claim 1, and thus incorporate all of the elements of Claim 1 and any intervening claim. One term at issue for purposes of my invalidity analysis is the "applicator head" term that first appears in Claim 1 below:

> [A]n *applicator head* coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

37. The Court has construed the term "applicator head" in the asserted claims of the '348 patent as: "a distal end portion of an ablation device that applies

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[3] The "Asserted Moisture Transport Claims" include all the remaining asserted claims of the '348 and '989 patents. For the sake of simplicity, throughout my report I will refer to the "Moisture Transport Patents" or the "Moisture Transport Family." This refers to the '348 and '989 Patents and, where applicable, to the other patents in this family. For the sake of simplicity, in my report I cite to the '348 patent with the understanding that the '348, '989, and the other patents of the Moisture Transport family all share one common specification.

energy to the uterine tissue."[4] Plaintiffs have asserted that the "applicator head" term reads on Minerva's Plasma Formation Array, or PFA.[5]

* * *

description support for a Plasma Formation Array (PFA) such as Minerva's since Plaintiffs assert that the full scope of the asserted claims encompasses Minerva's PFA. To look for this written description support, I reviewed at least the following documents: (i) the four corners of the Moisture Transport Patents' common specification; (ii) the May 8, 1998, MT Provisional to which every Moisture Transport Patent claims priority; (iii) the originally-filed claims of each application in the chain of priority for the Asserted Moisture Transport Patents; and (iv) for completeness, the other limitations of the Asserted Moisture Transport Patents.

C. State of the Art / Background Knowledge of a POSITA

44. By 1998, a POSITA would have known and understood that there were prior art surgical devices with a distal end designed to be inserted into a woman's cervical canal in a compressed state, and then subsequently expanded into an un-compressed state within the uterus, in order to perform some surgical procedure. These prior art devices generally had three major components: (i) a distal end designed to flare into a roughly triangular shape when in an uncompressed state in order to perform the procedure; (ii) a tubular main body designed to be inserted into

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[4] *See* Exhibit C to my report and D.I. 227.

[5] *See* Plaintiffs' April 12, 2017, Supplemental Claim Charts at 4-9.

the cervical canal; and (iii) a handle designed to hold and manipulate the device. Because the cervical canal is relatively narrow, the device is inserted into the uterus with the distal end in a compressed state. Once the device is fully inserted, the distal end is flared open into an uncompressed state in order to perform the surgical procedure. Unsurprisingly, the distal ends of these prior art devices were designed to conform to the substantially triangular shape of the uterus when in the uncompressed state.

45. Ortiz '496. For example, U.S. Pat. No. 5,358,496 to Ortiz et al. ("Ortiz '496") (MSI00043294) filed on September 30, 1993, shows such an electrosurgical device with a main body and distal end that deploys into a roughly triangular shape as shown in several of the figures:[9]

[9] *See also* Figures 1-4, 6-7, and 11-12; 3:3-24 ("The frame includes a pair of expandable fingers each comprising a flexible outer strip secured to the distal end of the actuator tube and a flexible inner strip secured to the distal end of the support shaft. The inner and outer strips are joined together at a distal finger tip. The fingers are flexed laterally outward in opposite directions by axial movement of the actuator tube relative to the shaft to provide a spatula-like platform for engaging the tissue. The fingers are selectively expandable into a tulip-shaped configuration with the finger tips spread apart and into a bulb-shaped configuration with the finger tips together. The fingers are expanded into the tulip-shaped configuration by movement of the actuator tube proximally relative to the support shaft and into the bulb-shaped configuration by movement of the actuator tube distally relative to the support shaft.") (emphasis added).

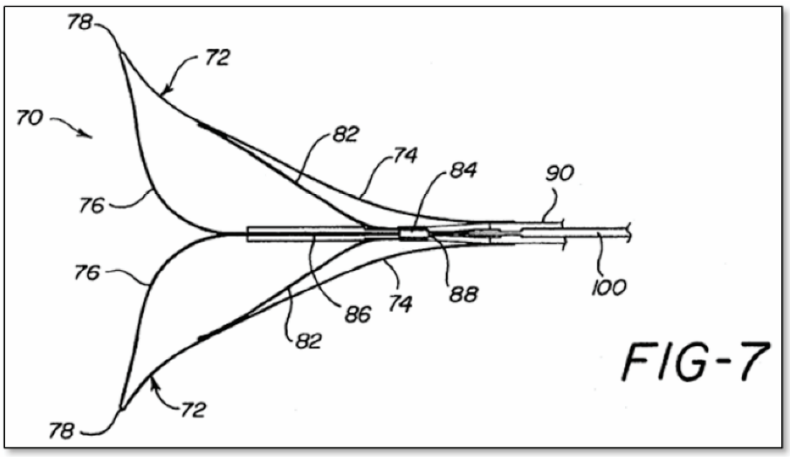

FIG-7

46. Yoon '091. Several other such devices are shown in U.S. Pat. No. 5,514,091 to Yoon ("Yoon '091") (MSI00043480) filed on May 25, 1994. This patent disclosed several expandable multifunctional manipulating instruments intended for various medical

procedures including the uterus.[10] *See* Yoon '091 at Figures 13[11] and 28A[12]:

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[10] *See* Yoon '091 at 22:14-17 ("In the expanded position, expandable portion 534a has a size and shape corresponding substantially to the size and shape of the uterus U . . .").

[11] *See also* 19: 52-67 ("A further modification of a multifunctional instrument according to the present invention is illustrated in FIG. 13 at 410, only the body assembly 412 for the instrument 410 being shown. Multifunctional instrument 410 is similar to multifunctional instrument 10 except that middle member 418 of instrument 410 is made of a non-elastic, non-stretchable, rigid material defining expandable portions 434 having a preformed predetermined shape. Multifunctional instrument 410 includes expandable portions 434a and 434b separated by a collar 420a with a collar 420b disposed proximally of expandable portion 434b, the collars 420a and 420b being similar to collars 20. Middle member 418 along expandable portion 434a has a preformed triangular or conical configuration particularly useful for uterine use and along expandable portion 434b has a preformed pear-shaped configuration. The middle member 418 is made as a collapsible bag, balloon or membrane of elastic or plastic material shaped to have the desired performed configurations along expandable portions 434a and 434b, and has connecting portions 419, which can be tubular, connecting expandable portions 434 and disposed within collars 420. The middle member 418 can be folded, rolled, crumpled or collapsed in the non-expanded position to facilitate introduction through a relatively small size anatomical opening.") (emphasis added).

[12] *See also* 9:18-24 ("As illustrated in FIG. 28A, expandable portion 1234 in the expanded position has a predetermined triangular or fan-shaped configuration in side view adjacent collar 1220. The triangular configuration of expandable portion 1234 is advantageous for universal use and, in particular, for use in uterine and kidney procedures and in the retroperitoneal space."); 9:53-61 ("FIGS. 29A-29E illustrate predetermined end view configurations for any of the expandable portions of FIGS. 28A-28D in the expanded position. FIG. 29A illustrates expandable portion 1234 of FIG. 28A in end view wherein the expandable portion 1234 has a relatively narrow oval predetermined

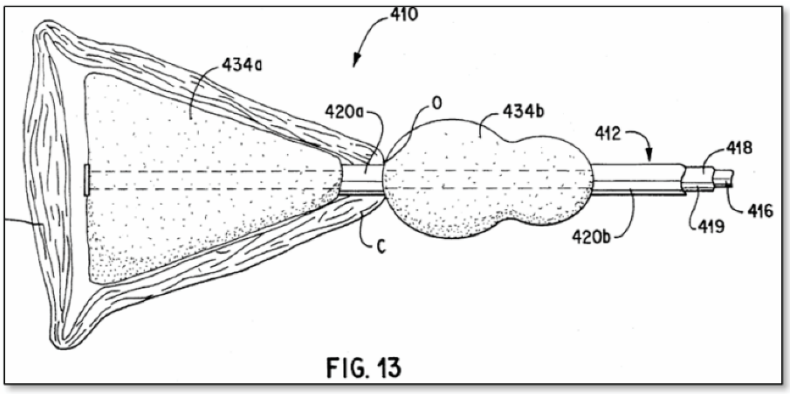

FIG. 13

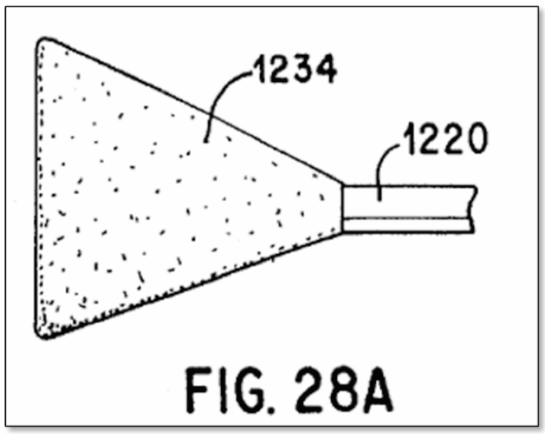

FIG. 28A

47. Nady-Mohamed '784. Yet another such device that deployed into a roughly triangular shape is shown in U.S. Pat. No. 5,353,784 to Nady-Mohamed ("Nady-Mohamed '784") (MSI00043265) filed on April 2, 1993:[13]

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configuration such that the overall configuration of the expandable portion is that of a flattened cone advantageous for universal use, in uterine and kidney procedures and in the retroperitoneal space.")

[13] *See* Claim 1 of Nady-Mohamed '784 ("a tube, having a single longitudinal bore, for insertion through a patient's cervix into the uterus; arm means for engaging the uterus, said arm means

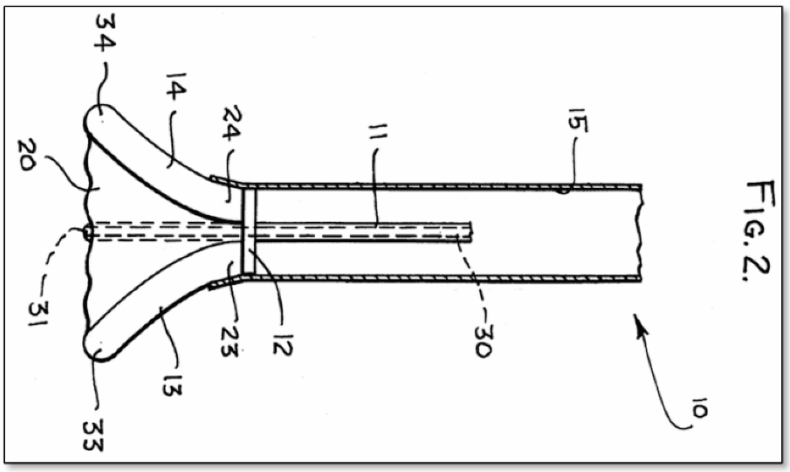

Figure 5 of Nady-Mohamed '784 discloses a hand grip.

48. Quint '044. Another such device that deployed into a roughly triangular shape is shown in U.S. Pat. No. 5,084,044 to Quint ("Quint '044") (MSI00165917) filed July 14, 1989. Quint '044 is identified in the "Background" section of the common specification of the Moisture Transport Patents. The prior art device taught by Quint '044 is an "[a]pparatus for performing thermal ablation of the endometrium of a uterus[.]"[14]The Abstract describes how the balloon on the distal end (i.e., the "inflatable member") is expanded from its collapsed position (for insertion into the uterus) into "an expanded position which approximates the shape and volume of a uterus." The "Description of the Preferred Embodiment" describes the tubular main body as, "formed by a thin walled, elongated

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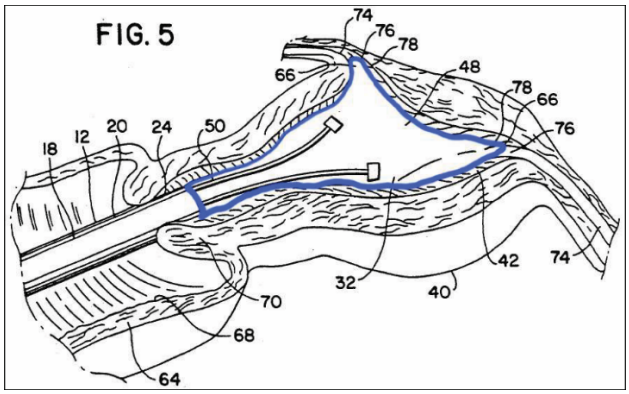
including two opposing, flexible arms slidably disposed within the distal end of said tube, said arms being curved such that they diverge to attain a shape which generally conforms to the contours of the lumen of the uterus upon extension of said arms from within said tube . . .) (emphasis added).

[14] Abstract.

cylindrical shaped member 18[.]" A POSITA would have understood that the device must also have had a handle or holding means for the surgeon to using when inserting or removing the device.[15]

49. In describing Figure 5 (shown below), the specification describes the shape of the distal end, and how it is designed to conform to the shape of the uterus when in expanded:

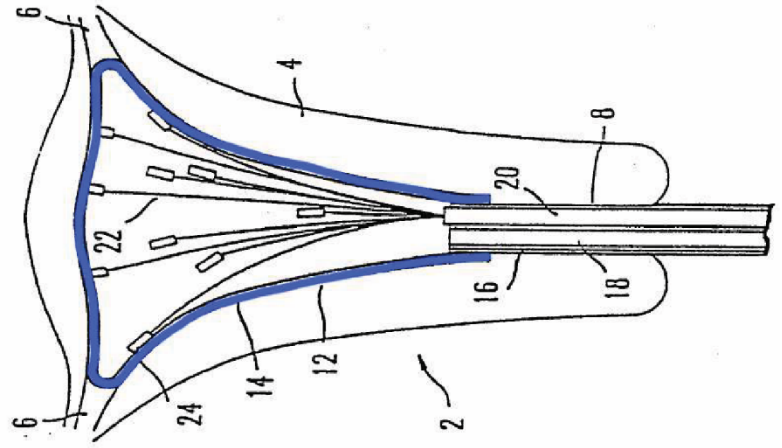
> The *inflatable member 32* is selected to be formed of an elastomeric material and *conform to the shape of the organ* under pressure derived from the fluid passed into the inflatable means. The extended arms 66 may become long and thin as shown in FIG. 5 in order to *conform to the shape of the uterus*.[16]



[15] This is true for all the devices I discuss in this section. A POSITA would know that the state of the art before the May 1998 priority date of the Moisture Transport Patents included endoscopic devices used in the uterus with a handle and a distal end that generally conformed to the shape of the uterus.

[16] 6:1-7; *see also* 6:39-41 ("wherein the inflatable means 32 is capable of expanding when filled with a fluid 26 from a collapsed position into an expanded position *which approximates the shape and volume of a uterus* 40").

50. Stern '470. Yet another such prior art electrosurgical device that was designed to be inserted into the cervical canal in a compressed state,[17] and then expanded into a substantially triangular shape in order to conform to the shape of the uterus,[18] is shown in U.S. Pat. No. 5,443,470 to Stern et al. ("Stern '470") (MSI00171139) filed April 14, 1993:



51. Figure 12 of Stern '470 (below) shows all three main components of the device, including the triangular distal end 190, which Stern '470 describes as "conforming to the inner surface of the endometrium [*i.e.*, the uterus]."[19] Stern '470 is identified in the "Background" section of the common specification of the Moisture Transport Patents.

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[17] *E.g.*, Fig. 2 (the distal end is item 14).

[18] *E.g.*, Fig. 1 (the distal end, item 14, is shown as conforming to the shape of uterus in its expanded state).

[19] *See also* 4:3-5 (The device of "FIG. 1 expands to conform to the endometrial surface to be treated").

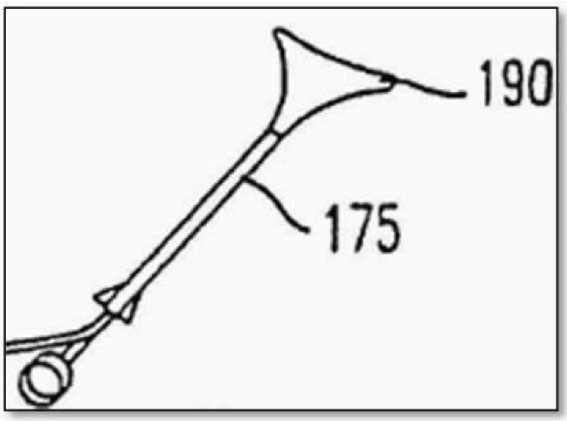

FIG. 12

52. In my opinion, a POSITA aware of even just this prior art—so before even reading the common specification of the Moisture Transport Patents—would already have understood that a well-known, basic and logical shape for an surgical instrument intended to be inserted and deployed inside a body cavity, such as a uterus, had three major components; namely: (i) a triangular or tulip-shaped distal end for applying energy to the uterine tissue; (ii) a tubular main body; and (iii) a handle.

53. As a named inventor on several patents, it is my understanding that a basic principle of patent law is that you cannot patent something that was already in the prior art. Therefore, a POSITA would have understood that, certainly by May 1998, a surgical device shaped to have (i) a roughly triangular distal end designed to conform to the shape of the uterus when in an uncompressed state; (ii) a tubular main body; and (iii) a handle—in and of itself—was not something that could be claimed as a new or patentable invention. Rather, the overall shape of a triangular distal end intended to conform to the shape of the

uterus, along with a tubular main body and a handle—*i.e.*, this "basic shape"—was a well-known and logical construct. Since the shape of the uterus is roughly triangular, it would dictate the shape of the expanded distal end, which necessarily had to collapse to a smaller diameter for insertion/removal. The surgeon also typically had to have a means of holding and manipulating the device, ergo some sort of handle.

54. The state of the art by May 1998 reinforces my opinion below that what the inventors were describing as *the invention* in the common specification of the Moisture Transport Patents was something more than this basic shape; namely, a novel moisture transport system where the RF applicator head had to draw moisture away from the tissue and into a permeable (or absorbent) array for subsequent evacuation.

55. In addition, a POSITA before May 1998 would have understood that an RF ablation device worked by applying radio frequency ("RF") energy (essentially an electrical current) to the target tissue by putting both positive and negative electrodes in contact with the tissue to be ablated. For example, the disclosures of the Stern '470 patent I discuss above specifically disclosed an RF endometrial ablation device with various patterns of electrodes all on the surface of the distal end.[20] Such a POSITA would have understood that applying a current in this manner was a form of "resistive" heating, as opposed to "thermal" heating that involves heating a liquid.[21]

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[20] *E.g.,* Stern '470 2:43-48.

[21] *See* 1:54-2:19 of the common specification.

D. The Teachings and Disclosures of the Moisture Transport Patents

1. The Common Specification

56. As I previously noted, every utility application in the Moisture Transport Family chain for the '348 and '989 patents (shown in the genealogy in Paragraph 116 below)—beginning in time with U.S. Patent Application No. 09/103,072, which was filed on June 23, 1998, and continuing through to the application that ultimately issued as the '989 patent (the last in the chain)—shares a common specification. Likewise the patents that issued from each of these applications in the chain also share the same common specification. To remain consistent with my earlier declarations, I will use the specification of the '348 patent as the representative and common specification for purposes of my validity analysis of the Asserted Moisture Transport Claims.

57. As a threshold matter, I note that in describing both the "First" and "Second" Exemplary Embodiments (so all embodiments), the common specification consistently refers to the working end of the ablation device (*i.e.*, the distal end that is inserted into the uterus by a surgeon and that actually ablates the uterine tissue) as the "RF applicator head."[22] Thus, my discussion of what the common specification discloses and teaches regarding the claim terms "applicator head" and "energy applicator" will be in terms of the "RF applicator head" of the common specification.

[22] *See* 2:51; 2:55; 3:4-25; 4:57-58; 8:8-9; 8:58; 10:15-17; 11:41-46; 11:60; and 12:1.

a. Overview of What a POSITA Would Have Understood From the Common Specification

58. In my opinion, a POSITA reading the common specification would have understood that what the inventors had possession of was a moisture transport system for an endometrial ablation device that requires the external electrode array of the RF applicator head (basically the outer cover) to be formed of a permeable or absorbent material in order to draw the moisture that builds up during the ablation away from the uterine tissue and into the array for evacuation. As the specification states: "It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site."

59. To start with, the common specification describes a device with three basic components: (i) an RF applicator head; (ii) a tubular main body; and (iii) a handle.[23]

60. A POSITA would have understood that it is the RF applicator head component that is the most technologically significant in that it is the component that actually performs the ablation. I note that the RF applicator head of the common specification itself has two main components: (i) an external tissue-contacting array that carries the electrodes on its surface (i.e., the "array"); and (ii) an expansion means for deploying the array into its uncompressed state.[24]

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[23] *See, e.g.*, Figs. 1 and 2; 4:55-63.

[24] *See, e.g.*, 12:5-8 (Referring to Figure 23 and stating, "Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.").

It is the external array that the common specification describes as either permeable or absorptive.

61. There are two embodiments described in the common specification. The "First Exemplary Embodiment" ("1st Embodiment") is described at 4:54-11:49 and by Figs. 1-20. The "Second Exemplary Embodiment" ("2nd Embodiment") is described at 11:50 to 18:67 and by Figs. 21-37B. Both embodiments refer to the distal end of the device as the "RF applicator head."[25] However, I note that the two embodiments use slightly different terminology when referring to the RF applicator head's external array (i.e., the tissue-contacting surface of the RF applicator head). The 1st Embodiment refers to the outer array as the "electrode carrying means 12," while the 2nd Embodiment—added roughly two years later in 1998[26]—refers to the tissue contacting surface of the RF applicator head as the "external electrode array 102a."[27] A POSITA reading the common specification would understand the inventors to be referring in each case to the outer array that contacts the tissue surface and on the surface of which the electrodes are formed. For simplicity, I will refer to the tissue-contacting surface of the RF applicator head in this report as the "external electrode array" or "array."

62. The common specification overall describes a particular solution to a particular problem that existed in the prior art. As a matter of biology, when uterine tissue is ablated, the tissue dehydrates and exudes moisture (essentially saline). The greater the amount of energy transferred to the tissue, the greater

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[25] 4:57 and 11:60.

[26] Truckai Decl., ¶ 12.

[27] *See, e.g.*, 4:59 and 12:5-6.

the extent of this dehydration and exuding of moisture. The resulting dehydration and exuding of moisture during the ablation procedure would thus cause a layer of moisture to build up between the uterine tissue and the exterior of prior art non-permeable applicator heads. The common specification teaches that the formation of this moisture layer is highly detrimental to the operation of the RF applicator head for several reasons.

63. First, the common specification teaches that the moisture layer is electrically conductive. Therefore, the RF energy (which manifests as electric current) that is intended to flow into the target tissue is instead diverted away from the tissue into the moisture layer:

> Moreover, in prior art RF devices the water drawn from the tissue creates a *path of conductivity* through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated.[28]

64. Second, the common specification teaches that another detrimental effect of the presence of a moisture layer is that the diversion of current into the moisture layer caused prior art devices to use more current than necessary to ablate the tissue. As the common specification teaches, "[m]oreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes."[29] A POSITA would have known that it was undesirable to use more current than necessary inside the human body.[30]

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[28] 2:9-12.

[29] 2:12-14.

[30] *See also* Truckai Decl., ¶ 8.

65. The common specification describes how yet another detrimental effect of the moisture layer is that heating the moisture layer turns the intended RF ablation into an unintended thermal ablation. Thermal ablation relies on the presence of moisture (*i.e.*, heated liquid) to ablate the tissue, which the common specification describes in multiple places as undesirable and less subject to control:

> The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes *thermal* ablation to continue well beyond the desired ablation depths.[31]

66. A POSITA would understand the common specification to be teaching away from the use of thermal ablation techniques as less subject to control. For example, the common specification describes how the undesirable "passive heating" of the liquid can result in either "too much or too little tissue" being ablated.[32] Thus, the inventors framed the problem addressed by their invention as a need to "eliminate" the formation of a moisture layer at the tissue/device interface during the ablation procedure. As the common specification states:

> It is therefore desirable to provide an ablation device which *eliminates* the above-described problem of steam and liquid buildup at the ablation site.[33]

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[31] 2:15-19; *see also* Exhibit F, (Websters Ninth, 1990) at 1224 ("thermal . . . of, relating to, or marked by the presence of hot springs <~waters>").

[32] 2:20-24.

[33] 2:25-27.

67. The common specification describes in detail and in several places how to solve this problem of steam and liquid buildup between the tissue and the electrodes on the exterior of the device. Specifically, the invention solves the problem by requiring the exterior of the RF applicator head to be made of a *permeable* fabric (a "mesh") or absorbent material (e.g., a "open cell sponge") in order to draw the moisture away from the surface electrodes and into the RF applicator head for subsequent evacuation (i.e., a moisture transport system).[34]

68. Moisture Transport. Thus, a POSITA reading the common specification would understand this moisture transport system using a permeable (or absorbent) array to be a fundamental characteristic of every embodiment. A POSITA would understand that for an RF ablation device, contact between the electrodes and the tissue is necessary for the claimed invention to operate. The removal of the moisture layer permits the electrodes on the surface of the applicator head to remain in contact with the tissue during the ablation cycle. I discuss more detailed support for my opinions below. In my opinion, some portion of both positive and negative active electrodes would have to contact the tissue in order for current to flow and ablate the tissue.[35]

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[34] *See, e.g.*, 5:52-61 and 12:1-64; Fig. 26A.

[35] *See* my declarations at D.I. 205 ¶¶ 50-55 and D.I. 196 ¶¶ 36-45.

b. The Titles Support My Opinions Regarding What a POSITA Would Have Understood From the Common Specification

69. I observe that it is the May 8, 1998 MT Provisional that the Plaintiffs—and both Asserted Moisture Transport Patents—identify as the earliest filed application on which they rely for priority.[36] That May 8, 1998 MT Provisional is titled: "A *Moisture Transport* System For *Contact* Electrocoagulation."[37] This is consistent with my opinion that a POSITA would have understood that an RF endometrial ablation device relied on contact between external, surface electrodes of the array and the uterine tissue (i.e., the tissue/electrode interface). The title would have reinforced for a POSITA that a fundamental characteristic of the invention is to transport the moisture away from the tissue so that the external electrodes can better *contact* the tissue during the ablation. The solution required a permeable (or absorbent) array.

70. It further supports my opinion that every application in the MT family chain was titled "*Moisture Transport System* for *Contact* Electrocoagulation," with the exception of the '520 application, which was titled, "Method for Ablating and/or Coagulating Tissue Using Moisture Transport"—so even that one emphasized moisture transport.

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[36] Plaintiffs' Supplemental Responses and Objections to Minerva's Interrogatory No. 6; MSI00013511 ('348 patent, "Related Applications") and MSI00144535 (same).

[37] MSI00014943.

c. The Abstract Supports My Opinion Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

71. A POSITA would have understood the importance and emphasis placed on the need for a permeable or absorbent external electrode array, and the need to prevent a moisture layer from forming, from the "Abstract" of the common specification, which states:

> An apparatus . . . includes a metallized fabric electrode array which is substantially *absorbent and/or permeable to moisture* and gases such as steam . . . As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The *moisture permeability and/or absorbency* of the electrode carrying member allows the moisture to leave the ablation site so as to *prevent* the moisture from providing a path of conductivity for the current.

d. The Figures Support My Opinion Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

72. Next, a POSITA would have understood the Figures of the common specification to show the permeable nature of the external array, based both on

the drawing as well as the textual description of the drawing.[38] For example, see Figs. 23 and 26A below:

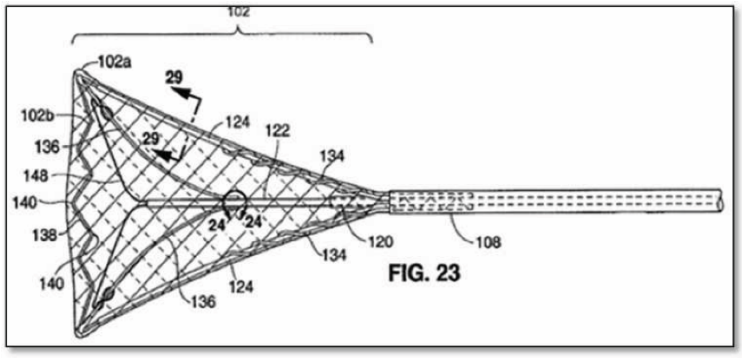


FIG. 23

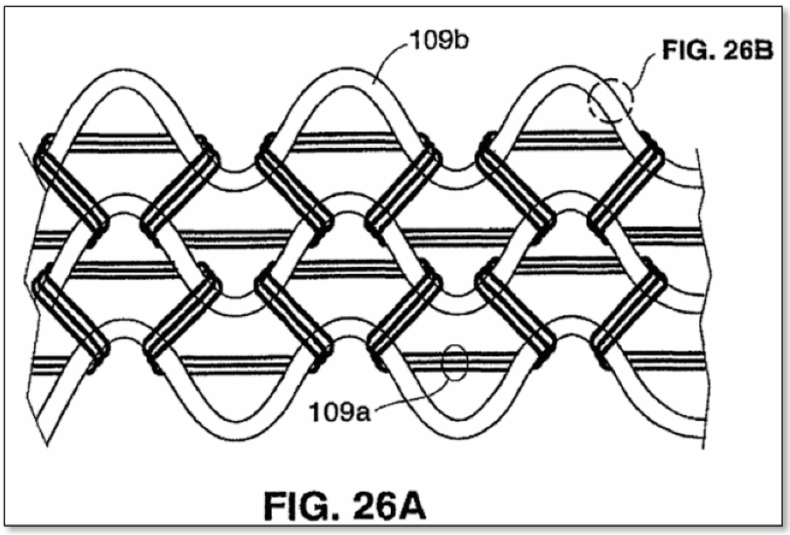


FIG. 26A

Figure 26A above shows an example of the permeable mesh that forms the external electrode array.

73. Also, a POSITA would have understood that Fig. 28 shows how the undesirable moisture is drawn

[38] *See, e.g.*, Figs. 23 (item 102a, the external electrode array), 26A-B, 27A-C, and 3:60-67 (describing the permeable "mesh" or "knit" of the external array).

into the RF applicator head, and how the removal of moisture is facilitated by means of holes in the outer flexures 124, and evacuated via central hypotube 122:

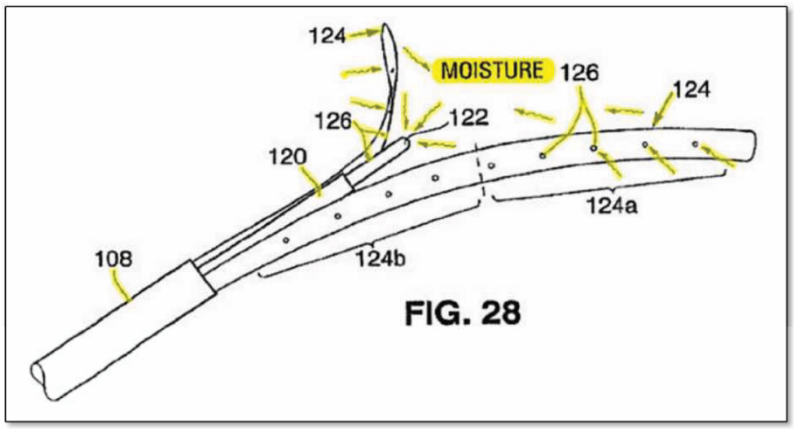


FIG. 28

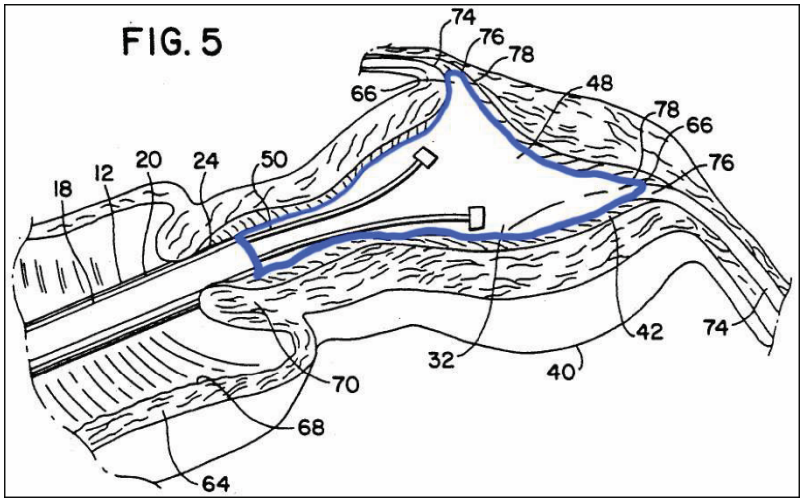
e. The "Background of the Invention" Supports My Opinions Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

74. A POSITA reading the "Background" section of the common specification would have understood that the inventors were describing the problems and drawbacks of prior art endometrial ablation devices in order to better explain, later in specification, how their invention overcomes those drawbacks. In other words, the inventors were distinguishing their invention from the prior art and thereby conveying to a POSITA what *not* to do—what I understand in patent law is sometimes referred to as "teaching away from" or "disparaging" the prior art.

75. In general, the "Background of the Invention" section disparages *thermal* ablation techniques that relied on heated fluid to thermally ablate the uterine

tissue, describing thermal techniques as "very passive and ineffective."[39]

76. The "Background" provides an example of a prior art endometrial ablation device (Quint '044) where the exterior of the applicator head is composed of a thermal balloon (item 32). The "Background" section of the Moisture Transport Patents' common specification describes how Quint '044's balloon 32 is expanded into contact with the endometrium and how it then "thermally" ablates the endometrium, as can be seen from Figure 5 from Quint '044:[40]



A POSITA in May 1998 reading the common specification of the Moisture Transport Patents and Quint '044's disclosure would understand that Quint '044's exterior balloon 32 is, by its nature, *non-permeable*. Consequently, such a POSITA would understand that

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[39] *See, e.g.*, 1:54-64 ("For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue."); also 1:31-33 and 1:65-67.

[40] *See* 1:33-38 of the Moisture Transport Patents' common specification.

Quint's balloon would retain the moisture in the uterine cavity—not remove it. As described in the common specification, such a result was undesirable. As previously noted, the primary motivation behind the invention of the Moisture Transport Patents was to "eliminate" that moisture layer.

77. The Moisture Transport Patents' "Background" section also discusses Stern '470, which is a prior art radio frequency (RF) apparatus for endometrial ablation. According to the Moisture Transport Patents' specification, Stern '470 teaches an RF applicator head whose exterior is composed of an expandable balloon (i.e., non-permeable) with electrodes on the surface of the balloon:

> U.S. Pat. No. 5,443,470 [Stern '470] describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.[41]

Indeed, this can be seen from Figures 4a,b and 6 of Stern '470, which shows electrodes on the exterior of Stern '470's expandable balloon:[42]

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[41] Moisture Transport Patents' common specification at 1:37-45.

[42] *See also* Stern '470 at 3:13-16 ("FIGS. 4a-b is a representation of an embodiment of an expandable member which uses a plurality of surface segments with each surface segment having a separate conductive surface and a temperature sensor"); and Stern '470 at 3:20-23 ("FIG. 6 illustrates an embodiment of the

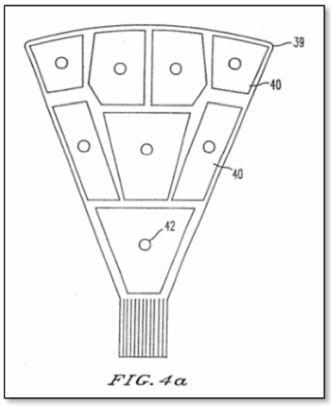

FIG. 4a

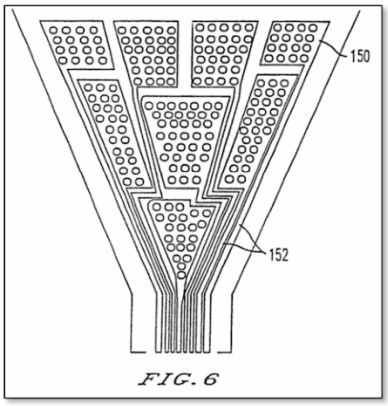

FIG. 6

78. After discussing these prior art devices, the Moisture Transport Patents' "Background" Section then discusses the various shortcomings of these prior art applicator heads—both of which were *non-permeable balloons*—by relating:[43]

- How they had trouble "controlling the ablation depth, which could only be done by "assumption";
- How "the heated fluid method [i.e., thermal ablation] is a very passive and ineffective heating process";
- How "[b]oth the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation"; and
- How a disadvantage of the prior art balloon is that "steam cannot escape" which could result in unintended burning.

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multi-segment element having perforated electrodes with illustrated power traces on the outside surface of the expandable member").

[43] 1:47-2:7.

79. The inventors go on to describe the fundamental problem with these prior art endometrial ablation devices, which was their inability to draw moisture away from the surface of the applicator head. This is because the exterior of the applicator heads of those prior art devices (both thermal and RF) were *non-permeable* balloons with no moisture transport mechanism (i.e., no mechanism for drawing moisture away from the tissue/electrode interface through a permeable array and into the applicator head).

80. As I have noted earlier in my report, a POSITA would have understood that when tissue begins to ablate, it exudes moisture (essentially saline).[44] That moisture creates a low-impedance path for electrical current (i.e., the current will tend to seek out a low-impedance path over a high-impedance path). The problem the inventors describe with prior art non-permeable RF applicator heads is that, once that moisture layer forms, the RF current that is supposed to travel through the uterine tissue to ablate it instead gets diverted into that undesirable low-impedance moisture layer (*i.e.*, the "path of conductivity"):

> Moreover, in prior art RF devices the water drawn from the tissue creates *a path of conductivity* through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated.[45]

81. A POSITA would understand the inventors to then elaborate on how that undesirable moisture layer, in turn, creates other problems. For example, the presence of the moisture layer causes more current

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[44] 10:59 ("As the endometrial tissue heats, moisture begins to be released from the tissue.").

[45] 2:9-13.

to be drawn from the electrodes than is necessary to perform the ablation, resulting in excess current (and therefore excess power) being used within the human body:

> Moreover, the presence of this current path around the electrodes *causes current to be continuously drawn* from the electrodes.[46]

As I already noted, a POSITA would understand that it is undesirable to use more current/power than necessary inside a patient's body.[47]

82. A POSITA would understand how the inventors next describe yet another drawback of non-permeable, prior art RF applicator heads; namely, how the current that is diverted into the undesirable moisture layer heats that liquid. Consequently, what was intended to be a "resistive" RF ablation turns into an unintended "thermal" ablation wherein again the depth of the ablation cannot be controlled, thereby causing "thermal ablation to continue well beyond the desired ablation depths":

> The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes *causes thermal ablation to continue well beyond the desired ablation depths*.[48]

83. As the next paragraph in the "Background" section describes, again with the prior art non-permeable applicator heads, the liquid retained in the cavity would heat up and there was no mechanism to

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[46] 2:10-14.

[47] *See also* Truckai Decl., ¶ 8.

[48] 2:15-19.

control the extent to which that heated liquid would ablate the tissue (i.e., lack of control over the depth of ablation). As a result, often either too much or too little tissue would be ablated:

> Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. *Thus, it is often the case that too much or too little tissue may be ablated* during an ablation procedure.[49]

84. A POSITA would understand that the inventors concluded the "Background" section by summarizing the goal and import of their invention, which was to make the external electrode array of their RF applicator head either permeable or absorbent in order to draw moisture into the array (i.e., the "moisture transport system"). In this manner, they eliminated the core problem of a moisture layer building up between the tissue and the electrodes on the surface of the array during the ablation, and thereby preventing current from being diverted from the tissue into that undesirable moisture layer:

> It is therefore desirable to provide an ablation device which *eliminates* the above-described problem of steam and liquid buildup at the ablation site.[50]

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[49] 2:20-24.

[50] 2:25-27.

f. The "Summary of the Invention" Supports My Opinions Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

85. A POSITA reading the "Summary of the Invention" section of the common specification would have understood that the inventors described their invention as an ablation device where moisture is drawn into a permeable (or absorbent) array and away from the tissue (i.e., the moisture transport system). In part, this is because the Summary literally starts this one-paragraph description by saying "[t]he present invention is . . . ." In addition, the Summary emphasizes how the array "*includes*" a fluid permeable elastic member, and how moisture "*is*" drawn into the array and away from the tissue. I note that this language does not say that the array "could be" or "may be" permeable, or that moisture "could be" or "may be" drawn into the array. In my opinion, this phrasing would inform a POSITA that drawing moisture into a permeable (or absorbent) array and away from the tissue was not optional:

> *The present invention is* an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a *fluid permeable* elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and *moisture*

generated during dehydration is actively or passively drawn into the array and away from the tissue.[51]

g. The "Detailed Description" Supports My Opinions Regarding What a POSITA Would Have Understood From the Disclosures of the Common Specification

86. A POSITA reading the Detailed Description section would first see that it starts by describing the invention in terms of two exemplary embodiments: "The ablation apparatus according to *the present invention* will be described with respect to two exemplary embodiments."[52]

87. The description of the 1st Embodiment teaches how the external electrode array is "permeable to moisture and/or which has a tendency to absorb moisture" and can be made of an absorptive "open cell sponge," or alternatively "a metallized fabric."[53] The specification also describes the "flow pathway" where moisture passes through the "permeable" array and is evacuated by means of a central hypotube 17 from within the array.[54]

88. The description of the 1st Embodiment also teaches the importance of contact between the tissue and the external electrodes of the array (i.e., with no

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[51] 2:32-45.

[52] 4:59-61.

[53] 5:52-65.

[54] 8:19-35.

intervening moisture layer).[55] As I noted above, a POSITA would have understood that the RF ablation apparatus being described worked by putting both positive and negative surface electrodes in contact with the target tissue.

89. A POSITA would also have understood other passages in the specification to again reinforce how the moisture transport system disclosed by the inventors was designed to draw moisture "away from the electrodes" through a permeable external electrode array:

> As the endometrial tissue heats, moisture begins to be released from the tissue. *The moisture permeates the electrode carrying member 12 and is thereby drawn away from the electrodes.* The moisture may pass through the holes 17a in the suction/installation tube 17 and leave the suction/insufflation tube 17 at its proximal end via port 38 as shown in FIG. 7. Moisture removal from the ablation site may be further facilitated b_5 the application of suction to the shaft 10 using the suction/insufflation unit 40.[56]

90. At column 11, a POSITA would have understood the inventors to again be reinforcing why it was important to use a permeable array to draw the moisture away from the tissue/electrode interface. Specifically, a POSITA would have understood that the formation of the moisture layer would be detrimental to the operation of the described ablation device because it would interfere with the device's ability to control the depth of ablation. As discussed earlier

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[55] 9:3-6 ("better contact"), 10:5-9 ("good electrode contact") and 10:15-19.

[56] 10:59-67.

when describing the problems with the prior art endometrial ablation devices in the "Background" section, the inventors here add more detail about how excess current diverted into that moisture layer would heat the moisture, thereby transforming what was intended to be an RF-only "resistive" heating of the tissue into an undesirable and less predictable "thermal" ablation:

> Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, *liquid build-up at the ablation site is detrimental* in that [it] provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. *This continued current flow heats the liquid* and surrounding tissue, *and thus causes ablation to continue by unpredictable thermal conduction means*.[57]

91. Next, a POSITA would understand the inventors to go on to describe how, by using a permeable array to draw moisture away from the ablation site, a physician could determine when the proper depth of ablation has been reached by monitoring the flow of current through the tissue (or put another way, by monitoring the impedance through the tissue):

> Tissue which has been ablated becomes dehydrated and thus decreases in *conductivity*. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the *impedance* at the tissue surface

[57] 11:1-8.

> becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant.[58]

92. Stepping through some concepts in this passage at column 11, a POSITA would have understood the inventors to be explaining that, as tissue becomes dehydrated (i.e., as the ablation progresses), it becomes less "conductive." Less conductive tissue means that it becomes harder for the current to flow through the tissue. Thus, as tissue ablates, the "conductivity" *decreases*. The specification also describes this effect in terms of "impedance," which is another way to think of this effect. In particular, as tissue dehydrates it becomes denser and starts to "impede" the flow of current. So a POSITA would have understood the inventors to be teaching that, as the tissue ablates, its "impedance" *increases*. Thus, in the parlance of the common specification, if the tissue conductivity decreases, then the impedance increases, and vice versa.

93. The rest of the passage above informs a POSITA that by "preventing liquid build-up" between the tissue and the surface electrodes, the current will flow through the tissue (instead of being diverted into a moisture layer). In the absence of a moisture layer, the physician can obtain an accurate reading of the

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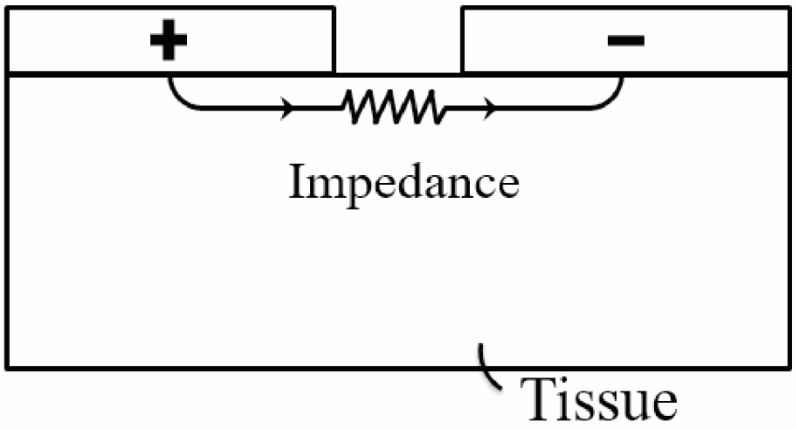
[58] 11:9-22.

impedance through the tissue. The impedance of the tissue is related to the degree to which it has been ablated. Thus, the *absence* of the moisture layer is a prerequisite for the invention to be able to accurately monitor and control the depth of ablation.

94. The drawing below graphically illustrates this concept. In the absence of a moisture layer, the current will flow as it should through the tissue, and therefore the actual impedance of the tissue (represented by the —ww— symbol) can be more accurately monitored.



95. A POSITA would understand that in the disclosures of column 11, the inventors were providing more detail regarding an advantage of their moisture transport invention mentioned earlier in the "Background" section of the common specification, where they stated:

> It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically

> discontinues ablation once the desired ablation depth has been reached.[59]

96. Further down in column 11, a POSITA would understand that the inventors were again contrasting the advantages of their moisture transport invention with the *drawbacks* of prior art RF ablation devices that failed to prevent the formation of a liquid layer at the tissue/electrode interface:

> By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, *the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance* reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.[60]

A POSITA would understand the inventors to be explaining how the presence of the liquid layer around the surface electrodes would distort any impedance reading, since the current would be diverted to that low-impedance liquid layer instead of through the tissue. Because the liquid layer is a low impedance layer, the physician would get a false reading indicating that the tissue is not yet sufficiently ablated, when in fact the correct depth of ablation may have been reached. The drawing below graphically illustrates this problem where the current flowing between positive and negative electrodes is diverted through the low-impedance liquid layer instead of through the tissue:

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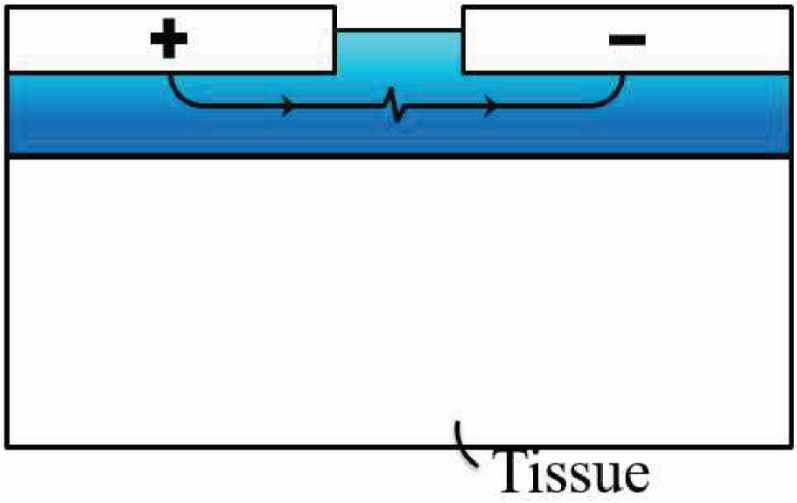
[59] 2:25-31.

[60] 11:22-28.



97. Also, as the inventors describe in the "Background" section, the diversion of the current through the liquid layer heats the liquid and turns what was intended to be an RF ablation into an undesirable and uncontrolled thermal ablation.

98. I understand that the inventors added the subject matter of the 2nd Embodiment two years after they disclosed the 1st Embodiment and after they had continued to refine their prototype.[61] In contrast to the 1st Embodiment, the 2nd Embodiment does not describe the use of an "open cell sponge" or other absorbent material as an option.[62] Rather, the 2nd Embodiment teaches that the external electrode array "is formed" of a permeable "mesh" without the use of optional language, such as "may be."[63] In addition, the

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[61] Truckai Decl., ¶ 12.

[62] Compare 5:52-60.

[63] *See* 12:9-11 ("the array 102a of applicator head 102 *is formed* of a stretchable metallized fabric *mesh*"); 12:49-50 ("The *mesh* may be configured in a variety of shapes, including . . ."); 12:9-64 (repeatedly describing the external electrode array as a

2nd Embodiment drops any mention of "passive" moisture removal and instead describes the use of suction (i.e., *active* moisture removal) to draw the moisture into the array. The 2nd Embodiment also adds additional holes along the outer flexures, as illustrated in Figure 28 below:[64]

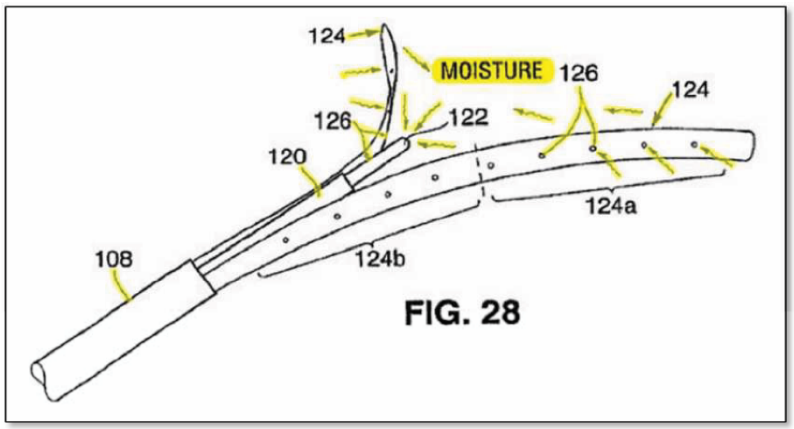

FIG. 28

A POSITA would understand that these changes allowed the device to even more efficiently draw moisture into the permeable external array and away from the tissue.

99. The common specification also informs a POSITA that the array must be permeable in other ways. For example, it describes suction/insufflation tube 17 as a dual-use tube. The common specification teaches and illustrates that, at one point during the operation of the device, the central tube 17 is used to flow CO2 into the uterine cavity (see the arrow just

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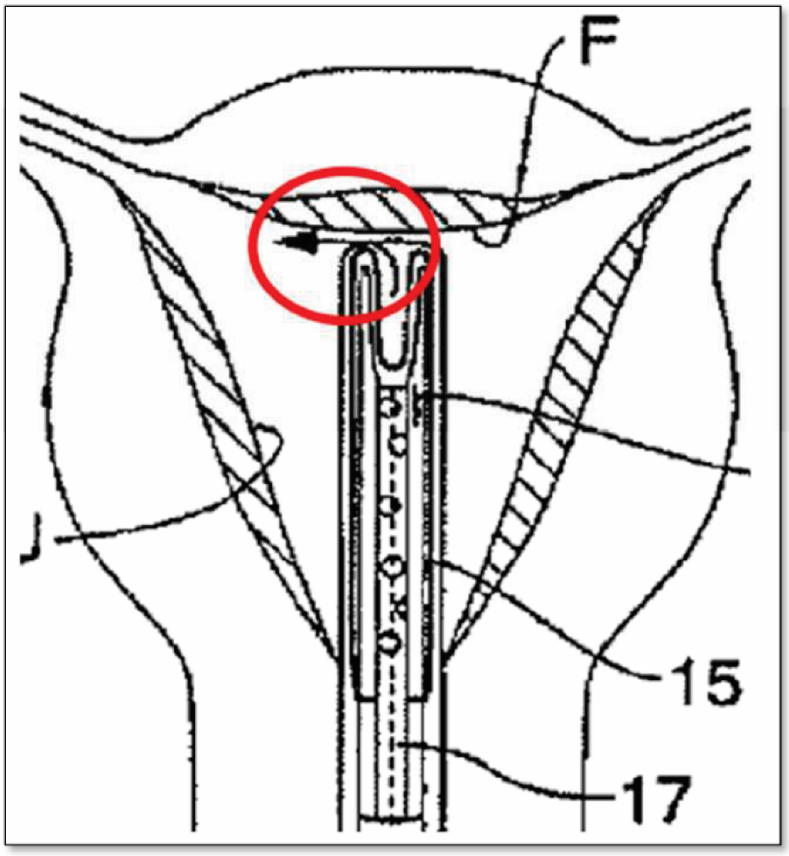
permeable "mesh" and preferably as a "knit"); 15:22-23 (describing "the *porosity* of the array fabric"); also for example Fig. 26A.

[64] *See also, e.g.,* 13:15-18, 18:40-52; Figs. 23 (item 102a), 26A-B, 27A-C, and 28.

below the fundus "F" in Fig. 6).[65] Importantly, the common specification teaches how suction/insufflation tube 17 is located *inside* the RF applicator head:



A POSITA would understand that in order to flow CO2 in through tube 17 (which sits *inside* the array) and have that gas flow out and into the uterine cavity, by necessity the array must be permeable—and the specification so states:

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[65] *See also* 9:29-39 ("carbon dioxide gas is introduced into the tube 17 via the port 38, and it enters the uterine cavity, thereby expanding the uterine cavity").

> If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/ insufflation tube 17 via the port 38. The insufflation gas travels through the tube 17, through the holes 17a, and into the uterine cavity through the *permeable* electrode carrying member 12.[66]

100. The common specification also teaches a POSITA that the other use of suction/insufflation tube 17 is to apply suction during the ablation itself to improve the contact between the electrodes and the uterine tissue:

> As described above, the application of suction to the RF applicator head 2 via the *suction/insufflation tube 17* collapses the uterine cavity onto the RF applicator head 2 and thus assures better contact between the electrodes and the endometrial tissue.[67]

A POSITA would again have understood that the use of suction through tube 17 to collapse the uterine tissue onto the surface of the RF applicator head (and thereby assure better contact between the tissue and the electrodes on the surface of the array) only works because the array is permeable. If the array were non-permeable, it would not have the described effect of collapsing the tissue into better contact with the electrodes.

101. Turning to the "electrode"-related terms such as "one or more electrodes," a POSITA reading the common specification would understand that what-

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[66] 8:19-35.

[67] 10:14-19 and 18:40-43 (describing how vacuum/suction is used to, "draw uterine tissue into contact with the array 102").

ever the number or pattern of electrodes, in every embodiment, all of the electrodes reside on the surface of the external electrode array. All of the electrodes are placed on the surface of the array in order to make contact with the uterine tissue. Put another way, the common specification does not disclose or describe any embodiment where one or more electrodes reside completely inside the array such that it (or they) do *not* contact the tissue during the ablation.

102. My opinion is consistent with what I described earlier; namely, that by the 1990s a POSITA would have understood that RF ablation devices designed for use in human body cavities were generally designed to have the electrodes contact the tissue in order to ablate it. These RF devices used "resistive" heating, as opposed to "thermal" heating of the tissue. As I discuss above, a POSITA would have understood that the focus of the invention described is to eliminate the intervening moisture layer by drawing the liquid into a permeable or absorbent external electrode array. This "moisture transport" system allows better contact between the electrodes on the surface of the external electrode array and the uterine tissue. It is the elimination of this undesirable moisture layer that allows the unimpeded contact between the surface electrodes and the tissue, thereby allowing a physician to better monitor and control the depth of ablation.

103. Working again through the common specification, a POSITA would note that the title of the common specification refers to the need for the electrodes to contact the tissue, (i.e., ". . . *Contact* Electrocoagulation").

104. The Abstract states, "[f]ollowing placement of the ablation device into *contact* with the tissue to be ablated[.]"

105. A POSITA would note that every Figure in the common specification relating to the electrodes shows the electrodes on the exterior surface of the RF applicator head such that they can contact the tissue. E.g., Figs. 2, 5A, 23 and 25A-B.

106. Although the common specification describes different shapes and patterns of electrodes, Figures 18 and 19A-C illustrate how nevertheless all of the electrodes are shown in direct contact with the uterine tissue.[68] See e.g., Fig. 19C (the electrodes are labeled "+" and "-", while the Tissue is labeled "T" below):

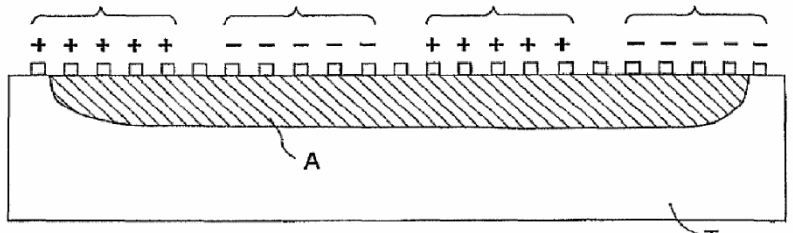

FIG. 19C

107. Next, a POSITA would understand that the "Background" section of the common specification describes the problems caused when the moisture layer creates an undesirable current path "around *the electrodes*." There is no language of exclusion or mention that this problem only relates to some subset of the electrodes. Thus, a POSITA would understand that not just one, but all of the electrodes are designed to contact the tissue. The common specification reinforces the importance of drawing moisture away from

[68] 3:34-41 (Description of figures, "showing electrode***s*** in contact with the tissue surface").

the electrodes, since otherwise the liquid build-up around them would obstruct contact with the tissue.[69]

108. Again, the "Summary of the Invention," which is describing "[t]he present invention," describes how the "electrode array" has "conductive regions thereon," and unambiguously states that, "[d]uring use, the electrode array is positioned *in contact* with tissue to be ablated."

109. A POSITA would take account of how the "Detailed Description" of the common specification teaches how "according to the present invention" the RF applicator head includes an array of electrodes "formed on the surface" of the array:

> Referring to FIGS. 1 and 2, an ablation device *according to the present invention* is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. Main body 4 includes a shaft 10. *The RF applicator head 2 includes* an electrode carrying means 12 mounted to the distal end of the shaft 10 and *an array of electrodes 14 formed on the surface of the electrode carrying means 12*.[70]

110. There is no statement to the contrary. There is no description in the common specification of one or more electrodes designed to reside only *inside* the applicator head, or designed *not* to contact the tissue. The clear statement put in terms of "the present invention" about the electrodes being "formed on the

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[69] 2:9-19 ("liquid *around the electrodes*"), 10:59-62, 11:1-8 ("Removal of the moisture from the ablation site prevents formation of a liquid layer *around the electrodes*.") and 11:22-28 (disparaging prior art RF devices that allow for "the presence of liquid *around the electrodes*").

[70] 4:54-61.

surface" would inform the POSITA that indeed, all electrodes relevant to the claimed invention are formed on the surface (and not the interior) of the array.[71]

111. The common specification goes on to describe how the electrodes: (i) may have a variety of patterns, (ii) can be made from a variety of materials, and (iii) can be formed on the exterior surface of the RF applicator head in a variety of ways. However, in every embodiment without exception the electrodes are formed on the tissue-contacting surface of the RF applicator head.[72] The common specification describes in detail how the electrodes can be formed on the surface of the array by plating the outer surface with gold or some other conductive material.[73]

112. The common specification goes on to reinforce the importance of how, "during use it is most desirable for the electrode*s* 14 on the surface of the electrode carrying means 12 to be held *in contact* with the interior surface of the organ to be ablated[.]"[74]It also describes various alternative ways to improve contact between the electrodes and the tissue by means of: (i) "spring members"; (ii) "a pair of inflatable balloons . . .

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[71] *See also* Fig. 5A and 5:40-41.

[72] 5:52-6:11 and 12:53-13:7 (describing a four-electrode surface pattern of the 2nd Embodiment).

[73] 12:9-48

[74] 2:40-41 ("During use, the electrode array is positioned in *contact* with tissue to be ablated,"), 3:35 ("ablation electrodes in *contact* with the tissue surface"), 3:39, 6:21, 8:47-49 ("Because during use it is most desirable for the electrodes 14 on the surface of the electrode carrying means 12 to be held in *contact* with the interior surface of the organ to be ablated"), 11:61-67, 12:5-8 and 18:33-34 ("deflecting mechanism 102b has deployed the array 102a into *contact* with the uterine walls.").

arranged inside the electrode carrying means 12;" or (iii) "the application of suction" to "draw the organ tissue towards the electrode carrying means 12 and thus into *better contact* with the electrodes 14."[75]

113. The common specification describes in detail the operation of the ablation device "according to the present invention." For example, it describes in detail the use of sensors to establish contact between the electrodes and the endometrium.[76] A POSITA would also understand that "[t]he second embodiment differs from the first embodiment primarily in its electrode *pattern*"—but not in the fundamental need to make contact with the tissue.[77] As with the 1st Embodiment, the RF applicator head is designed to "expand into contact with body tissue."[78] A POSITA would also understand that in describing the "Operation" of the endometrial ablation device, the need for "contact" between the electrodes and the tissue is never described as optional. Rather, the specification repeatedly discusses alternate and/or more effective ways to insure contact with the tissue.[79] Ergo, it follows that the electrodes are only being described as on the surface or exterior of the RF applicator head. I see no written description support for one or more electrodes

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[75] 8:47-9:6.

[76] 9:18-21 and 9:59-10:25 (refers in various places to "sufficient contact," "good contact," and "better contact").

[77] 11:50-58 and 12:1-8.

[78] 11:59-67; 15:16-45 (describing the "adjacent electrodes" at 15:21); Figs. 25A, 25B and 33.

[79] *E.g.*, 18:33-34 ("deployed the array 102a into *contact* with the uterine walls.") and 18:41-43 ("Suction helps to draw uterine tissue into *contact* with the array 102.").

designed to reside on the interior of the RF applicator head, or otherwise out of reach of the tissue.

E. Prosecution History of the Asserted Moisture Transport Claims

114. For purposes of my analysis, I was asked to assume that the Asserted Moisture Transport Patents have a May 8, 1998, date of invention, which corresponds to the earliest application filed with the Patent Office to which both asserted patents claim the benefit (i.e., priority):

Asserted Patent	Asserted Date of Invention
'348 Patent	May 8, 1998[80]
'989 Patent	

115. I am informed that Plaintiffs have asserted even earlier dates of conception, but that those dates do not apply to this analysis regarding validity based on the written description and enablement requirements, which focus on the applications actually filed with the Patent Office and their respective actual filing dates.

F. The Moisture Transport Family: Dates of Applications and Patents

116. I understand that the Asserted Moisture Transport Patents are related to U.S. Application No. 09/103,072 ("the '072 Application") through a string of related patent filings. The '072 Application was filed on June 23, 1998, and issued as U.S. Patent No. 6,813,520. The '072 Application, in turn, claims the benefit of U.S. Provisional Application No.

[80] '348 patent, 1:12-13; '989 patent, 1:14-16.

60/084,791.[81] The following diagram depicts the Moisture Transport Family:

Every utility application in the Moisture Transport Family shares a common specification, as I have previously indicated.

117. I note that all of the issued claims in the moisture transport family chain, starting with the issued claims of the '072 Application through the '506 Application included limitations regarding the permeable nature of the external array of the applicator head, or the need for suction through the applicator head (which necessarily requires the applicator head to be permeable).

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[81] '348 patent, 1:1-13; '989 patent, 1:1-16.

118. On August 8, 2013—15 years after the May 8, 1998 priority date—Plaintiffs filed the application that issued as the '348 Patent. The '348 patent was the first patent in the family chain to issue with claims that no longer included any permeability-related limitations, and thus were broader and more generic with respect to the nature of the "applicator head" element. Likewise, the later '989 patent also included broader and more generic claims with respect to the nature of the "energy applicator" element.

G. The NovaSure Product

119. Plaintiffs' endometrial ablation system has two basic components: a disposable handpiece and an RF Controller. It is the handpiece—and in particular the distal end—that is at issue for purposes of my analysis, as it is the distal end that corresponds to the "applicator head" and "electrode" elements of the Asserted Moisture Transport Patents. The NovaSure uses only RF energy to ablate tissue.

120. The NovaSure device includes an external electrode array that is formed from a metalized, porous fabric. All electrodes (both positive and negative) are formed on the exterior, tissue-contacting surface of the array. Steam and moisture are continuously from the tissue as it dessicates by the use of suction. This moisture is drawn into the applicator head, and is then sucked out through a central hypotube.[82] This use of a fluid-permeable fabric on the exterior of the applicator head to draw moisture from the interface between the fabric and the uterine tissue

[82] *See* D.I. 87, Exhibit 11 (NovaSure Operator Manual) at MSI00017165

during the ablation is fundamental to the NovaSure design.[83] [84]

121. During a procedure, the NovaSure device delivers up to 180 watts of ablation energy to the patient during a procedure.[85] Consequently, ablated tissue tends to stick to the NovaSure's RF Applicator head during a procedure.[86]

122. Also, I am aware that some physicians have found the Minerva device to be easier to insert into a uterus than the NovaSure device. On at least one occasion, a physician made "many attempts" to insert a NovaSure device but was "unable to gain access to the cavity with the NovaSure device." This physician was able to complete the procedure with the Minerva device.[87]

123. The following is an image of the RF applicator head from a NovaSure device (see positive and negative electrodes in gold on one face of the RF applicator head):

[83] *Id.*; *see also* D.I. 29 (Redacted Evantash Decl.) at ¶ 11.

[84] *See also* my previous descriptions of the NovaSure product from my prior declarations in this case.

[85] *See* D.I. 87, Exhibit 11 (NovaSure Operator Manual) at MSI00017165

[86] *See* the video at MSI00002329.

[87] *See* HOL-MIN_005788

H. Minerva's Plasma Formation Array (PFA)

124. Minerva's Endometrial Ablation System ("EAS") has two basic components: a disposable handpiece and a Controller. It is the handpiece—and in particular the distal end—that is at issue for purposes of my analysis, since it is the distal end that Plaintiffs assert falls within the scope of the "applicator head"- and "electrode"-related elements of the Asserted Moisture Transport Patents.

125. Minerva's handpiece employs what is in my experience a very unique Plasma Formation Array ("PFA") to ablate uterine tissue. Initially, I note that Minerva's Pre-Training Study Manual includes a relatively layman-friendly tutorial of the scientific and technical concepts underlying Minerva's technology (such as a discussion of plasma, argon, ionization and RF energy).[88] I also note here the description in Mr. Truckai's declaration regarding the design, development, and technology built into Minerva's PFA.[89]

126. The distal end of Minerva's handpiece (a.k.a. the PFA) deploys an external sealed silicone membrane into the uterine cavity—not a permeable fabric, mesh, or other porous material as is used for the exterior of the NovaSure's applicator head.[90] Minerva's sealed silicone membrane is fluid-tight and non-

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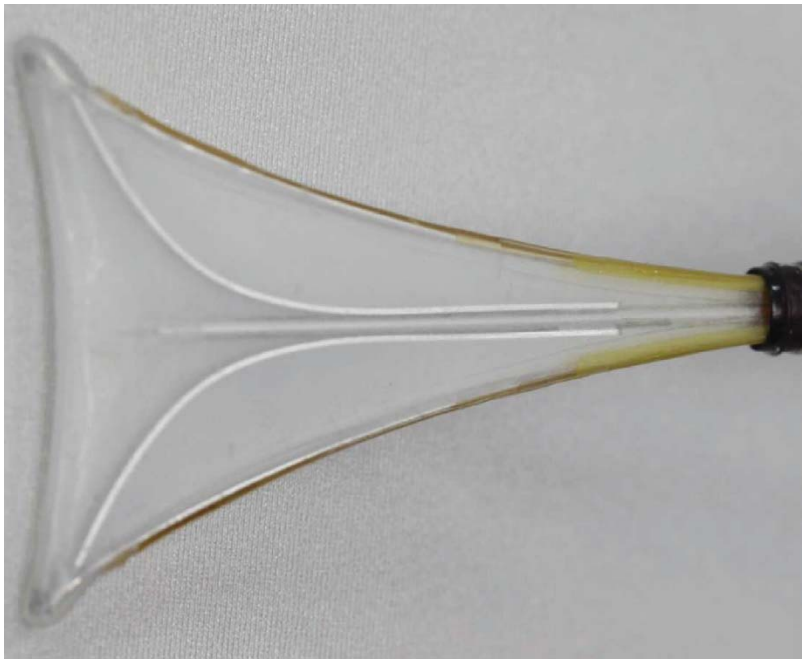
[88] D.I. 87, Ex. 10 at pages MSI00004508-13

[89] Truckai Decl., ¶¶ 31-41.

[90] D.I. 87, Ex. 10 at MSI00004500 ("The Minerva Endometrial Ablation System uses bipolar RF electrical current . . . to ionize argon (AR) gas, which is fully contained and circulating within a *sealed* silicone membrane covering the plasma formation array ("PFA").").)

permeable.[91] Below is an image of Minerva's working end complete with the external sealed silicone membrane:



Unlike the NovaSure's/'348 patent's moisture transport system, Minerva's EAS does not draw moisture through an external permeable cover and away from the uterine tissue. This is because Minerva's external membrane is sealed and fluid tight, as described in at least in the following documents:

- Pre-Training Study Manual at MSI00004500: "During the ablation cycle, the Minerva system does not proactively evacuate the liquid

[91] D.I. 87, Ex. 12 (Minerva Operator Manual) at MSI00001987 ("Argon gas is fully contained within the Minerva Disposable Handpiece silicone membrane and is not released into the uterine cavity during the ablation procedure.")

contents from the uterine cavity. These liquids remain in the uterine cavity, are heated by the membrane, and used to ablate the endometrial tissue that is not in direct contact with the membrane. This is especially helpful when the cavity is distorted by small intracavitary or intramural pathology or when the uterine cavity lacks axial symmetry . . . the Minerva Endometrial Ablation System uses bipolar RF electrical current at a frequency of 480 kHz to ionize argon (AR) gas, which is fully contained and circulating within a sealed silicone membrane covering the plasma formation array (PFA)."[92]

- Minerva Operator Manual at MSI00001987: "Intracavitary moisture is not removed during the energy delivery process. Argon gas is fully contained within the Minerva Disposable Handpiece silicone membrane and is not released into the uterine cavity during the ablation procedure."[93]
- HDD Pneumatics at MSI00002337: "The perforation detection subsystem . . . verifies that no other cavity leak exists, *such as a perforation in the plasma membrane*."[94]

As I discuss further below, Minerva's design operates in a different way to exploit and benefit from the

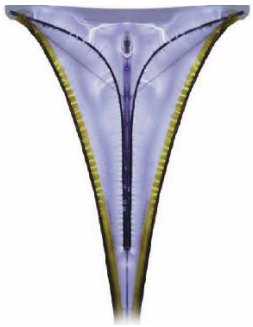
[92] D.I. 87, Ex. 10.

[93] D.I. 87, Ex. 12.

[94] D.I.87, Ex. 82.

presence of a moisture layer between the exterior of its sealed silicone membrane and the uterine wall.[95]

127. Plasma Argon Gas. In Minerva's design, there is only a single return electrode (of a first polarity) on the outer surface of the membrane.[96] The other electrode (of opposite polarity) is located inside the non-permeable silicone membrane.[97] The inner electrode never makes contact with the uterine tissue. Prior to and during the ablation, the Minerva EAS pumps an inert Argon gas into the sealed silicone membrane. The inner electrode ignites the Argon within the membrane, turning it into a glowing blue plasma:[98]



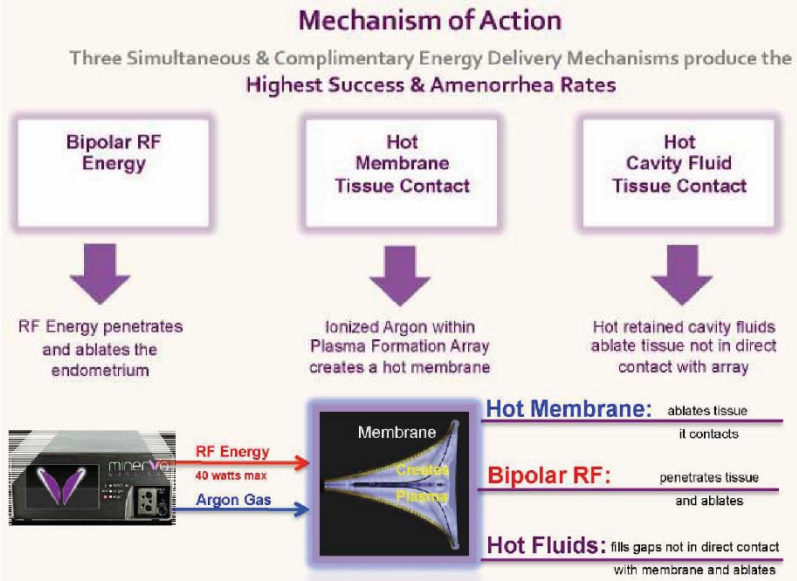
[95] *See also* my previous declaration in this case describing the operation of Minerva's device.

[96] D.I. 87, Ex. 12 (Minerva Operator Manual) at MSI00001986 ("A single tissue contacting electrode resides on the outer surface of the membrane.").

[97] D.I. 87, Ex. 12 ("[T]he expanded frame acts as the internal electrode inside the membrane.").

[98] D.I. 87, Ex. 12 at MSI00001986-87 ("Argon gas inside the membrane is ionized by the RF energy delivered by the internal electrode . . . The heat generated from the ionized argon plasma allows for the controlled transfer of energy to the uterus for the purpose of endometrial tissue ablation."); also D.I.87, Ex. 10 (Pre-Training Study Manual) at MSI00004508-09.

The plasma forms filaments of electricity that emanate a visible blue light. These filaments can be seen by the naked eye in Minerva videos that show its PFA in operation.[99] Minerva's EAS ablates tissue using hot membrane tissue contact, hot cavity fluid tissue contact, and also RF energy mechanisms of action as illustrated below:[100]



128. Primary Thermal Mechanism. Due to the physics of the Minerva device, once the plasma is ignited, the filaments seek out and heat points along the inside of the sealed silicone membrane that are adjacent to tissue that requires additional ablation.[101] That heat is conducted through the sealed silicone

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[99] MSI00001654 (D.I. 87, Ex. 7) (PFA in operation); MSI00120135 (D.I. 87, Ex. 19) (PFA in saline); and MSI00002251 (D.I. 87, Ex. 15) (PFA in egg white).

[100] D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004499 & 4507.

[101] Truckai Decl., ¶¶ 21-30.

membrane and heats the adjacent uterine tissue. This heating is demonstrated in the attached video of the Minerva PFA in operation heating egg white.[102] Minerva's distal end uses a thermally-conductive silicone membrane to uniformly heat the uterine tissue.[103]

129. In my opinion, a POSITA would not understand the common specification to teach or disclose any plasma formation mechanism. I am not aware of any other endometrial ablation device (including the NovaSure product) that uses anything like the plasma formation mechanism used by Minerva's EAS design.

130. Secondary Thermal Mechanism. In the process of ablating the tissue, the moisture layer builds up along the exterior of Minerva's sealed silicone membrane and along the tissue/membrane interface as described or illustrated by the documents below:

- MSI00168258 (D.I. 24): video attached as Exhibit 16 to the Cohn Declaration at 16-22 seconds.
- D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004500: Minerva's system "does not proactively evacuate the liquid contents from the uterine cavity. These liquids remain in the uterine cavity, are heated by the membrane, and used to ablate the endometrial tissue that is not in direct contact with the membrane. *This is especially helpful when the cavity is distorted by small intracavitary or intramural pathology or when the uterine cavity lacks axial symmetry.*"

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[102] MSI00002251, (D.I. 87, Ex. 15)(egg white video).

[103] D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004500.

- D.I. 87, Ex. 12 (Minerva Operator Manual) at MSI00001987: "Intracavitary moisture is not removed during the energy delivery process.") and MSI00001989 ("The combination of the heat conducted through the membrane wall from the plasma to adjacent endometrial tissue, retained heated intra-cavitary moisture that fills gaps around the surface of the array, and a small amount of bipolar RF current traveling through the target tissue (and resultant heat), results in the ablation endometrial tissue.").

131. Minerva's PFA heats the moisture layer in the interstices of the tissue, thereby facilitating a more uniform ablation, and using roughly 40 Watts.[104]

132. In contrast to Minerva's maximum output of 40 watts, the common specification describes how an:

> EEPROM within the RF generator system converts the length and width to a set power level according to the following relationship:
>
> P=LxWx5.5
>
> Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.[105]

Thus, for an ablation area of 6.5cm in length and 4.5cm in width (for example), the invention described

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[104] D.I. 87, Ex. 10 (Pre-Training Study Manual) at MSI00004500 ("creating a uniform and reproducible ablation") and MSI00004517 ("system operates at a max power output of 40 watts").

[105] 15:67-16:6.

in the common specification would require 160 watts (6.5 x 4.5 x 5.5).

133. Tertiary Mechanism. Small amounts of RF current from the filaments that emanate from the internal electrode pass across the dielectric silicone membrane by a phenomenon known as capacitative coupling. These filaments are attracted to a low impedance area where the tissue needs further ablation. While the energy is not large, it is important in treating tissue needing further ablation and in adding to the uniformity of the ablation. This is the "scanning" phenomenon described in Minerva's PFA patents that contributes greatly to the uniformity of the ablation.

134. Because the Minerva device uses its patented plasma formation technology to ablate the tissue and also uses a relatively small amount of RF current to control the depth of ablation, it also more evenly ablates the tissue using only a quarter of the power of the NovaSure device. Consequently, Minerva's device does not generate nearly the same level of steam as the NovaSure product, and therefore (unlike the NovaSure) steam does not need to be actively evacuated during the procedure. In other words, no moisture transport system as described in the Moisture Transport Patents is needed. This is illustrated in a side-by-side video of both devices.[106] With Minerva's PFA, the heated liquid layer is retained and used productively to gently ablate the millions of tiny internal folds of uterine tissue.

I. Minerva's Patented PFA Technology

135. Here I incorporate by reference the facts set out by Mr. Truckai regarding Minerva's PFA patents.

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[106] D.I. 87, Ex. 25

I have confirmed that during prosecution of its PFA patents, Minerva's disclosed the entire common specification by virtue of disclosing the '520 patent to the Patent Office.

136. Exhibit D to this Report includes claim charts comparing a claim of each of the Minerva's PFA patents to Minerva's EAS. In my opinion, Minerva's EAS practices the claims cited in Exhibit D.

137. In my opinion, Minerva's EAS embodies each of the three Minerva PFA patents included in Exhibit D.

J. A POSITA Would Not Find Written Description Support For the Full Scope of the Asserted Moisture Transport Claims In the Common Specification

1. Lack of Written Description

138. In my opinion, a POSITA reading the common specification would not find that the inventors were in possession of the full scope of the Asserted Moisture Transport Claims. The disclosures of the common specification fail to reasonably convey to a POSITA that the inventors had possession of the subject matter that Plaintiffs' assert falls within the scope of the asserted claims, for all of the above reasons which I summarize below, and therefore the Asserted Moisture Transport Claims are invalid.

139. A POSITA would understand the common specification to disclose that the inventors had possession of only a species of RF applicator head with a *permeable* or *absorbent* tissue contacting surface into which moisture is drawn in order to prevent formation of a moisture layer along the exterior surface of the device (i.e., the moisture transport system). The

common specification describes in detail the numerous reasons why the failure to "prevent" or "eliminate"

* * *

DEFINITIONS

> **Plasma**. In general, this disclosure may use the terms "plasma" and "ionized gas" interchangeably. A plasma consists of a state of matter in which electrons in a neutral gas are stripped or "ionized" from their molecules or atoms. Such plasmas can be formed by application of an electrical field or by high temperatures. In a neutral gas, electrical conductivity is non-existent or very low. Neutral gases act as a dielectric or insulator until the electrical field reaches a breakdown value, freeing the electrons from the atoms in an avalanche process thus forming a plasma. Such a plasma provides mobile electrons and positive ions, an acts as a conductor which supports electrical currents and can form spark or arc. Due to their lower mass, the electrons in a plasma accelerate more quickly in response to an electric field than the heavier positive ions, and hence carry the bulk of the current.

There is no equivalent disclosure of even a plasma in the common specification of the Moisture Transport Patents; much less any description or enabling disclosure for how to harness the use of such a plasma into the distal end of an endometrial ablation device.

167. I further observe that Minerva's accused PFA design uses a non-permeable (i.e., fluid tight) balloon to enclose the Argon gas. This use of a non-permeable balloon designed to *retain* the moisture layer, and that primarily relies on a *thermal* ablation, is not enabled and is indeed *contrary* to the teachings of the common

specification. As I note above, the common specification repeatedly disparages and teaches away from each of these features. Yet, due to the physics of its plasma formation array (e.g., the "scanning" mechanism whereby the plasma filaments actually seek out the less ablated tissue as described in Minerva's PFA patents), Minerva's PFA is able to achieve what is in my opinion a gentle, even and well-controlled delivery of energy, which is customized to the patient's uterus, in contravention of the teaching in the common specification that thermal techniques were less subject to control. Thus, this further informs my opinion that the common specification of the Moisture Transfer Patents lacks an enabling disclosure.

3. A POSITA Would Understand That Minerva's "Scanning" Mechanism Was Not Predictable.

168. The fact that Mr. Truckai was surprised by the physics of how his plasma formation array was able to achieve a more gentle and even ablation further supports my opinion that a POSITA would have had to engage in undue experimentation to enable the full scope of the Asserted Moisture Transport Claims. As Mr. Truckai relates, the "scanning" mechanism described in detail in his PFA Patents was an unpredictable benefit of how the plasma filaments would very rapidly seek out the low-impedance paths through the target tissue.[126] I agree based on my experience that this would not have been a predictable result at the time based on Mr. Truckai's novel use of plasma formation technology to ablate tissue through a thin-walled dielectric membrane. I understand my

[126] Truckai Decl., ¶¶ 30, 36, 41; *see, e.g.*, columns 11-12 and Figs. 9A-D of U.S. Pat. No. 8,372,068.

opinions in this regard relate to *Wands* factor number 7.

169. I further note that Mr. Truckai describes other discoveries in the course his PFA development, such as:[127]

> In one aspect of the invention, FIG. 10 is a circuit diagram representing the steps of the method in FIGS. 9A-9D which explains the discovery that return electrode 205 can have a small surface area and not be subject to significant heating. In
>
> * * **

O. Conclusions Regarding the Asserted Pressure Sensor Patent

262. Thus, the Asserted '183 Patent Claims are invalid because they (i) fail to meet the written description requirement; and independently because they (ii) fail to meet the enablement requirement.

XI. RESERVATIONS OF RIGHTS

263. Although I have cited particular evidence in this report, I have done so to assist in understanding my conclusions and the bases for them. This report does not discuss every piece of evidence that could be used to support by conclusions. Accordingly, 1 may affirm, update, or modify my opinions based on such other evidence as necessary.

264. I may make additions or modifications to my conclusions in the future, based on new evidence that is presented to me. For trial, I may prepare diagrams,

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[127] The '068 Patent at 12:47-50.

charts, and other demonstratives to illustrate my conclusions or the technology at issue.

Dated: June 30, 2017

/s/ Robert Tucker
Dr. Robert Tucker, Ph.D., M.D.

[1] IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-JFB-SRF

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,

Defendant and Counterclaimant.

HIGHLY CONFIDENTIAL –
ATTORNEYS' EYES ONLY

Videotaped Deposition of
CSABA TRUCKAI
Wednesday, October 25, 2017
1:02 p.m.

650 Page Mill Road
Palo Alto, California

Janis Jennings, CSR No. 3942, CCRR, CLR

[2] VIDEOTAPED DEPOSITION OF CSABA TRUCKAI, taken on behalf of the Plaintiffs and Counterdefendants, at WILSON, SONSINI, GOODRICH & ROSATI, LLP, 650 Page Mill Road, Palo Alto, California, beginning at 1:02 p.m. on Wednesday, October 25, 2017, before Janis Jennings, Certified Shorthand Reporter No. 3942, CLR, CCRR.

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[4] INDEX OF EXAMINATION

WITNESS: CSABA TRUCKAI

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[7] INDEX TO EXHIBITS

[8] PALO ALTO, CALIFORNIA; WEDNESDAY, OCTOBER 25, 2017; 1:02 A.M.

THE VIDEOGRAPHER: Good afternoon. We are on the video record on October 25, 2017, and the time is 1:02. My name is Reynaldo Abesamis Jr.; I'm the legal videographer. And the court reporter today is Janis Jennings.

This is the beginning of disc labeled No. 1 for the deposition of Csaba Truckai in the matter of Hologic, Inc., versus Minerva Surgical. The case number is 15-1031-SLR-SRF. We are located today at I Wilson Sonsini in Palo Alto, California, 94304.

Counsel, please identify yourself for the record, beginning with the questioning attorney.

MR. RAJANI: Assad Rajani, Arnold & Porter Kaye Scholer, on behalf of the plaintiffs.

MS. ELSON: Vera Elson of Wilson Sonsini Goodrich & Rosati on behalf of defendant Minerva Surgical.

Also, in the caption, the initials of the judge you read are incorrect. It's no longer Sue Robinson. It's Judge Bataillon.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

* * *

[41] BY MR. RAJANI:

Q. How are you aware of that?

MS. ELSON: Instruction not to answer. Privileged.

BY MR. RAJANI:

Q. What do you understand is the current challenge on the validity of the patents-in-suit?

MS. ELSON: Same objection. Instruction not to answer. Privileged.

THE WITNESS: I'm taking my counsel advice.

MR. RAJANI: And I want to make clear: Your objection is that what his understanding is of the current attack on the validity of the patents-in-suit is privileged?

MS. ELSON: If you can answer that question without revealing the substance of any attorney-client communication, you may do so.

Objection. Form. Legal conclusion.

THE WITNESS: Repeat the question, please, one more time.

BY MR. RAJANI:

Q. What is your understanding of the current basis for the challenge of the validity of Hologic's patents-in-suit?

MS. ELSON: Same instruction.

[42] THE WITNESS: I don't think it very simply can be answered. It's a number of issues.

BY MR. RAJANI:

Q. What are those issues?

MS. ELSON: Overly broad. Objection. Form. Legal conclusion.

THE WITNESS: Again, I'm not a legal expert. That's why I'm – it's difficult, you know, to say without you asking specific questions regarding what are those items.

BY MR. RAJANI:

Q. You just said it was a number of issues; right?

MS. ELSON: Same objection.

THE WITNESS: That's my understanding.

BY MR. RAJANI:

Q. What's your understanding of what those issues are?

A. I would have to make – sorry.

MS. ELSON: No. Go ahead. I was just going to give the same objection.

If you can answer that question without revealing the substance of any attorney-client communication, you may do so.

THE WITNESS: I can't answer.

[43] BY MR. RAJANI:

Q. Are you aware if Hologic's patents-in-suit have been challenged as not enabled?

MS. ELSON: Same objection.

THE WITNESS: Explain. What does it mean "enabled"?

BY MR. RAJANI:

Q. You don't know what it means to not enable?

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: It's a legal term. I'm not a lawyer. So if you explain to me what does it mean, then I will answer.

BY MR. RAJANI:

Q. I'm asking if you have an understanding as to what "enablement" is.

MS. ELSON: Objection. Legal conclusion.

THE WITNESS: I would just have to guess.

MS. ELSON: I have to ask for a pause. I'm suddenly not getting the realtime. Can we go off the record a moment?

MR. RAJANI: Sure.

THE VIDEOGRAPHER: We are going off the record, and the time is 1:41.

(Off the record.)

[44] THE VIDEOGRAPHER: We are now going back on the record, and the time is 1:43.

BY MR. RAJANI:

Q. Mr. Truckai, are you aware that your declaration is being cited in support of Minerva's invalidity arguments in this case?

MS. ELSON: If you can answer that question without revealing the substance of any attorney-client communications, you may do so. Otherwise, I instruct you not to answer.

THE WITNESS: Actually, I don't know its use. I don't know how it is being used.

BY MR. RAJANI:

Q. You prepared Exhibit 1, your declaration, and you're not sure how its being used in the case?

MS. ELSON: Asked and answered.

BY MR. RAJANI:

Q. Go ahead and answer.

MS. ELSON: Same – same instruction. If you can answer that question without revealing the substance of any attorney-client communication, you may do so. Otherwise, I instruct you not to answer.

THE WITNESS: I am taking my counsel advice.

///

[45] BY MR. RAJANI:

Q. You didn't ask if your declaration was related to the invalidity of the patents-in-suit?

MS. ELSON: Instruction not to answer.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Have you ever discussed the invalidity of Hologic's patents-in-suit with anyone?

MS. ELSON: Same instruction not to answer. Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Let's go to page 1 of your declaration, paragraph 2. The last sentence refers to a copy of your CV; right?

A. I'm sorry?

Q. The last sentence refers to your CV; correct?

A. Which part are you talking about? I'm sorry.

Q. Paragraph 2, the last sentence.

A. Yes.

Q. "A copy of my CV."

A. That's right.

THE VIDEOGRAPHER: Counsel, I'm going to [46] ask that you turn off your cell phone. It's causing some interference, some static.

MS. ELSON: Mine?

THE VIDEOGRAPHER: Both of you.

MS. ELSON: Mine was muted.

THE VIDEOGRAPHER: I'm going to turn off mine too.

THE WITNESS: I could put on airplane mode

MR. RAJANI: I think he's saying interference, so I'll just turn mine off.

I'm going to mark as Exhibit 2 a document titled "Csaba Truckai," and it's Bates-labeled MSI00299668 through 669.

(Exhibit 2 marked for identification.)

BY MR. RAJANI:

Q. This is a copy of your CV; right?

A. Yes.

Q. When Novacept was formed, you were Novacept's vice president of R&D; right?

A. Correct.

Q. In what year was Novacept formed?

A. It's not a simple answer. So the company was started in 1993 as Envision Surgical System. Envision Surgical System.

Q. Envision?

[47] A. E-n-v-i-s-i-o-n.

Then the company changed its name to Acuvasive.

Q. How do you spell that?

A. A-c-u-v-a-s-i-v-e, I believe, but I have to check.

Q. Okay.

A. I know we pronounce it "Acuvasive."

Q. Do you know when you became Novacept's vice president of R&D?

A. When we changed the name to Novacept.

Q. And is it at the time of the name change you became the vice president of R&D?

A. Yes.

Q. Do you know approximately when that was?

A. I would have to guess. 1995, '96, something like that.

Q. You also became Novacept's president; correct?

A. Later on, yes.

Q. When was that?

A. I don't recall the precise date.

Q. Did you remain Novacept's president until 2000?

A. Until 1999; December, I believe.

[48] Q. In March of 2000 you joined Novacept's board of directors?

A. No. I was on the board prior to that.

Q. How much earlier were you on the board of directors of Novacept?

A. Since Envision. So Envision, Acuvasive and continuation of Novacept. So I was – if you're looking at the company, the company started as Envision Surgical System. Through the name changes, I was always on the board.

Q. Did you remain on Novacept's board of directors until it was acquired by Cytyc, C-y-t-y-c, in 2004?

A. I was.

Q. You're a founder of Minerva; correct?

A. Yes.

Q. You founded Minerva in 2008; correct?

A. I believe so.

Q. Who named it Minerva?

MS. ELSON: Objection. Form.

THE WITNESS: I think it was the CFO at the time came up with the name.

BY MR. RAJANI:

Q. Do you know why the company was named Minerva?

[49] A. Because Minerva is a goddess, you know, for woman. So since the company purpose is to develop a product which helps and improve woman healthcare, that's why we ended up having the name Minerva.

Q. Was there a particular type of product that Minerva had in mind at its – strike that.

Was there a particular type of product that the company had in mind at its founding?

MS. ELSON: Objection. Form.

THE WITNESS: Endometrial ablation product.

DEPOSITION REPORTER: One more time.

THE WITNESS: Endometrial ablation product.

BY MR. RAJANI:

Q. So is it fair to say that you began developing Minerva's endometrial ablation product as soon as it was founded?

MS. ELSON: Objection. Form.

THE WITNESS: It's not a simple answer to that.

BY MR. RAJANI:

Q. Explain it to me.

A. In 2006 we formed a company, and we were looking at all kind of different technologies. The company was Arqos, and – but that was just IP holding company. So we were developing a orthopedic [50] product, and part of the development was – I would call it collateral damage. You know, we discovered –

DEPOSITION REPORTER: "I would call it –

THE WITNESS: Collateral. You know –

MR. RAJANI: Collateral damage.

DEPOSITION REPORTER: Oh.

THE WITNESS: – invention, collateral invention. We realized that the technology has multiple applications, including the endometrial ablation field.

BY MR. RAJANI:

Q. What was the name of the company formed in 2006 that you just mentioned?

A. Argos.

Q. How do you spell that?

A. A-r-q-o-s.

Q. Is Argos listed in Exhibit 2?

A. It was really – it had no employees, so it was an IP holding company. And Argos split into multiple companies. We split the IP into multiple fields. It was a true IP holding company.

Q. Was it an LLC?

A. That's correct.

MS. ELSON: Objection – objection. Form.

[51] THE WITNESS: That's correct.

BY MR. RAJANI:

Q. Were there other members of Argos?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Who?

A. John Shadduck, Bruno Strul. I have to look at the names. The company is no longer in existence, so . . .

Q. What was Bruno's last name?

A. Strul.

Q. How do you spell that?

A. S-t-u-r-l [verbatim].

Q. S-t-u-r-l? Okay.

So is it fair to say that you began developing Minerva's endometrial ablation product prior to Minerva being formed?

A. No –

MS. ELSON: Objection. Form.

THE WITNESS: No, it's not.

BY MR. RAJANI:

Q. Why do you say that?

A. Because we developed many technologies, and the technology eventually which is Minerva has [52]

nothing got to do with Arqos technology, really. It wasn't part – you know, it was just us developing the orthopedic product. We realized that, you know, there are other things that are beyond Arqos.

Q. You were the president of Minerva at its founding in 2008?

A. Yes.

Q. You were the president of Minerva until May 2011; correct?

A. It sounds about right.

Q. And that was when Mr. Clapper took over?

A. Correct.

Q. As the president of Minerva, what were your job responsibilities at a high level?

MS. ELSON: Objection. Form.

THE WITNESS: Give general direction to the company, put the management team in place, raise the sufficient funds, and just like many startup company, you know, do whatever it takes.

BY MR. RAJANI:

Q. With respect to the endometrial ablation product that Minerva was working on, as the president of Minerva, did you have any specific responsibilities – strike that.

As the president of Minerva, did you have [53] any specific job responsibilities with respect to its endometrial ablation product?

MS. ELSON: Objection. Form.

THE WITNESS: The company is an endometrial ablation company, so not precisely. I'm trying to –

what – I mean, I – I describe my function of the company. It's a single-product company, so its not like, you know . . .

BY MR. RAJANI:

Q. Thanks for clarifying. So the job responsibilities you just described earlier, all of those relate to Minerva's endometrial ablation product; correct?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. You were also the CEO of Minerva until May 2011; right?

A. Correct. So I have them the same time, the president and the CEO.

Q. As the CEO what were your job responsibilities?

MS. ELSON: Objection. Form.

THE WITNESS: Same as the president.

///

[55] Q. So you were not an employee of Minerva at its founding?

MS. ELSON: Objection. Form.

THE WITNESS: I was a consultant CEO.

BY MR. RAJANI:

Q. You have never been an employee of Minerva?

A. I was always a consultant CEO.

Q. Your understanding is you have never been an employee of Minerva?

A. I have never received a salary from Minerva as a normal employee.

Q. Did you consider yourself an employee of Minerva at any time?

MS. ELSON: Objection. Form.

THE WITNESS: I was a consultant. Consultancy.

BY MR. RAJANI:

Q. You're currently a member of Minerva's board of directors?

A. Yes, I am.

Q. How long have you been on Minerva's board?

A. Since inception.

Q. And your title is currently director at Minerva?

A. Board –

[54] BY MR. RAJANI:

Q. Is it fair to say that your job as president and CEO included managing the company?

MS. ELSON: Objection. Form.

THE WITNESS: That was my primary responsibility.

BY MR. RAJANI:

Q. Is it fair to say that as president and CEO your job included setting the strategic direction of the company?

A. Yeah. Somewhat. That is one of the functions.

Q. And as Minerva's CEO and president, is it fair to say that your job included implementing that strategic direction?

MS. ELSON: Objection. Form.

THE WITNESS: My job was to execute the company plan.

BY MR. RAJANI:

Q. Did you bill by the hour when you served as president and CEO of Minerva?

A. Yes.

Q. So you billed those hours through Hermes, H-e-r-m-e-s, Innovations, LLC?

A. Correct.

[56] MS. ELSON: Objection. Form.

THE WITNESS: Board of directors, member of the board of directors.

BY MR. RAJANI:

Q. Do you have any – excuse me – do you have any written agreement with Minerva by which you have agreed to serve on its board of directors?

A. I – actually, I am not sure. I don't think so.

Q. Do you understand that one of your duties as a member of the board is to hire and fire CEOs?

MS. ELSON: Objection. Form.

THE WITNESS: Yeah.

BY MR. RAJANI:

Q. Do you understand that one of your duties as a member of the board is to assess the direction of Minerva's business?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Do you understand that as a member of Minerva's board of directors you owe a fiduciary duty to Minerva?

MS. ELSON: Objection. Form. Legal conclusion.

[57] THE WITNESS: Yes.

BY MR. RAJANI:

Q. How often does Minerva's board of directors meet?

A. Every two to three months.

Q. When the board of directors meets, do you attend in person?

MS. ELSON: Objection. Form.

THE WITNESS: Not all the time.

BY MR. RAJANI:

Q. How often would you say you attend in person?

MS. ELSON: Same objection.

THE WITNESS: I would say most of the time, but I don't have a precise count.

BY MR. RAJANI:

Q. Who – who presents at these meetings?

A. The –

MS. ELSON: Objection. Form.

And I would just caution the witness not to reveal any attorney-client communications. If you can otherwise answer the question, go ahead.

THE WITNESS: Company management.

BY MR. RAJANI:

Q. Is it only the CEO who presents, or is

[58] there more than one person that presents?

A. Company –

MS. ELSON: Same – same instruction.

THE WITNESS: Company management.

BY MR. RAJANI:

Q. Is it more than one person from company management that presents?

A. Yes.

MR. RAJANI: I am going to mark as Truckai Exhibit 3 a document titled "Minerva Surgical Board of Directors Meeting," and it is labeled MSI00298766 through MSI00298845.

(Exhibit 3 marked for identification.)

MR. RAJANI: And I'll also mark as Truckai Exhibit 4 another document titled "Minerva Surgical Board of Directors Meeting," and this one is labeled MSI00298846 through MSI002- – 298953.

(Exhibit 4 marked for identification.)

MR. RAJANI: Here you go.

BY MR. RAJANI:

Q. Are Exhibits 3 and 4 examples of slides that are presented during board of directors meetings?

A. It appears so.

Q. Do you have any reason to believe that they [59] are not the slides presented at board of directors meetings?

MS. ELSON: Objection. Form.

THE WITNESS: I don't know. I haven't reviewed them, so I can't comment on them.

BY MR. RAJANI:

Q. Do you want to take some more time to look at them?

A. Sure.

MR. RAJANI: Oh, and I can represent to you that these were produced by Minerva, as shown by the Bates numbers at the bottom corner.

BY MR. RAJANI:

Q. And let me actually ask you to go to just the cover of Exhibit 3. The document has a date of Tuesday, April 18, 2017; right?

A. Correct.

Q. Do you specifically remember attending this meeting?

A. I have to review the material.

Q. Go ahead.

A. I think so, but if you are looking at the board and you have multiple board meetings and the subject matter is pretty much the same, so very – very repeat – very repeated information. So [60] probably I was. If not, I called in.

Q. And we can speed this along. Do you remember the specifics of what was said or wasn't said at any – at either the meeting on April 18th, 2017 or February 14th, 2017?

MS. ELSON: And I'm just instructing the witness –

Well, let me put it this way, Counsel. Would you care to rephrase that question to exclude any privileged communications?

BY MR. RAJANI:

Q. I will just start with – I am only asking for a "yes" or "no," whether you remember the specifics of what was discussed at either of those meetings.

A. Somewhat. Not everything. I mean, I would have to refresh, go back, look at the board meeting minutes and . . .

Q. Let's go to the second page of Exhibit 3. The Bates number ends in 767 in the bottom corner, and the title of the slide is "Agenda."

Do you see that?

A. Yeah. Yes, I can.

Q. On what topics are board members briefed when the board of directors meets?

[61] MS. ELSON: Objection. Form.

THE WITNESS: On all, but in various extent, so it changes board meetings to board meetings. So even though you have the agenda, this one doesn't describe how much time we spent on each subject.

BY MR. RAJANI:

Q. And just before when you said "On all," you were referring to all of the nine topics listed on the agenda?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Topic No. 3 reads, "IP Lawsuit Update."

Do you see that?

A. Yes, I can.

Q. Without going into what the substance of that update is, why is – why are members of the board given an IP lawsuit update?

MS. ELSON: I'll instruct the witness not to answer. Privileged.

BY MR. RAJANI:

Q. Do you understand as a member of the board why you would be given updates as to IP lawsuits?

MS. ELSON: Instruction not to answer. [62] Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Who presents the legal updates at the Minerva board meetings?

MS. ELSON: Same – same instruction. Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Does Mr. Clapper provide that update, or is it someone else in management?

MS. ELSON: Same instruction. Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Has the board ever discussed Minerva's legal strategy in this case?

MS. ELSON: Same instruction. Privileged.

THE WITNESS: I'm taking my – my counsel legal advice.

BY MR. RAJANI:

Q. As a member of the board, do you ever provide any comments about this litigation?

MS. ELSON: Same instruction. Privileged.

THE WITNESS: I'm taking my counsel legal advice.

[63] BY MR. RAJANI:

Q. Do you currently have an ownership interest in Minerva by virtue of owning company stock?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, I do.

BY MR. RAJANI:

Q. You own approximately 6 percent of Minerva's stock?

MS. ELSON: Objection. Form.

THE WITNESS: Probably you know better than I do. I don't know.

BY MR. RAJANI:

Q. You're not sure how much you own?

A. No.

Q. Do you own any shares of Minerva where your ownership interest has not yet vested?

MS. ELSON: Objection. Form.

THE WITNESS: I may have some warrants, so . . .

DEPOSITION REPORTER: "I may have some –

THE WITNESS: Warrants. Warrants.

BY MR. RAJANI:

Q. What is that?

MS. ELSON: Objection. Form.

THE WITNESS: It's a stock where you have [64] the right to buy it at a certain price.

BY MR. RAJANI:

Q. Like an option?

A. It's like a – it's not an option. It's a warrant.

Q. How do you spell that word?

A. W-a-r-r-a-n-t.

Q. And through – how did you come to – do you own any warrants for Minerva stock?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. How did you come to own those?

MS. ELSON: Objection. Form.

THE WITNESS: That was a financing, and prior to financing the company, they made some bridge funds, and a note came with a warrant.

BY MR. RAJANI:

Q. So this is something you would have received at the time when Minerva was founded?

A. No.

MS. ELSON: Sorry. I didn't get my objection in. Objection. Form.

Go ahead.

///

[65] BY MR. RAJANI:

Q. When did you receive those warrants?

A. 2011, I would say.

Q. Do you invest in Minerva through any of your other businesses?

MS. ELSON: Objection. Form.

THE WITNESS: No. It's in my own money.

BY MR. RAJANI:

Q. Are you an investor in Vivo Capital?

A. No, I am not.

Q. You're a founder and managing member of Hermes, H-e-r-m-e-s, Innovations LLC; right?

A. Correct.

Q. Is it your company?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. How much of the company do you own?

MS. ELSON: Objection. Form.

THE WITNESS: It's an LLC. It's an equal distribution to members.

BY MR. RAJANI:

Q. Did you say it was an equal distribution?

A. I don't know precisely what the distribution structure is, but, you know, the [66] members are equal.

Q. Has Hermes provided Minerva services regarding Minerva's intellectual property?

A. Yes.

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. What kind of services has it provided?

MS. ELSON: And if you can answer that question without revealing the substance of any attorney-client communication, you can do so. Otherwise, I instruct you not to answer.

THE WITNESS: We license certain patents to Minerva.

BY MR. RAJANI:

Q. Is that the only work Hermes has done with Minerva?

MS. ELSON: Same instruction.

THE WITNESS: Hermes also provided CFO service and IP service, which comes with the – licensing the patent to the company.

BY MR. RAJANI:

Q. Does Hermes provide any services regarding whether any inventions are patentable?

MS. ELSON: I instruct you not to answer. [67] Privileged.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. That's what you said at your last deposition, so I would assume that the privilege is waived. What did you mean in your prior testimony?

A. That we license –

MS. ELSON: Same instruction. You don't have to answer. Privilege.

BY MR. RAJANI:

Q. Are you going to answer?

A. I'm taking my counsel advice.

Q. Has Hermes provided any services to anyone relating to Hologic's patents-in-suit?

MS. ELSON: Same instruction not to answer. Privilege.

THE WITNESS: I'm taking my counsel advice.

BY MR. RAJANI:

Q. Has Hermes provided any services to anyone relating to the NovaSure device?

MS. ELSON: If you can answer that question without revealing the substance of any attorney-client communications, you may do so. Otherwise, I instruct you not to answer.

THE WITNESS: No.

[68] BY MR. RAJANI:

Q. With respect to Hermes providing any services to anyone regarding Hologic's patents-in-suit, can you answer that question without disclosing any attorney-client communications?

MS. ELSON: I'm sorry.

MR. RAJANI: Let me ask the question again.

MS. ELSON: Yeah.

THE WITNESS: Yeah.

BY MR. RAJANI:

Q. Has Hermes provided any services to anyone relating to Hologic's patents-in-suit?

MS. ELSON: And if you can answer that question without revealing the substance of any attorney-client communications, you may answer that question. Otherwise, I instruct you not to answer.

THE WITNESS: I can't answer.

BY MR. RAJANI:

Q. Has Hermes provided any services to anyone relating to this lawsuit?

MS. ELSON: Again, if you can answer that question without revealing the substance of any attorney-client communications, you may answer that question. Otherwise, I instruct you not to answer.

* * *

[73] Am I pronouncing that correctly?

A. Correct.

Q. M-e-d-r-e-s.

Has Medres –

DEPOSITION REPORTER: I'm sorry.

MR. RAJANI: M-e-d-r-e-s.

DEPOSITION REPORTER: Thank you.

BY MR. RAJANI:

Q. Has Medres been involved in any way with the design of any alternate Minerva handles?

MS. ELSON: Objection. Form.

THE WITNESS: First, I don't know that there is an alternate design, and I'm not aware if Medres, you know, would do any of that.

BY MR. RAJANI:

Q. Okay. Let's go to page 19 of your declaration, which was Exhibit 1.

MS. ELSON: I'm sorry. Page 19 or paragraph 19?

MR. RAJANI: Page 19, paragraph 49.

MS. ELSON: Thank you.

BY MR. RAJANI:

Q. The second sentence of paragraph 49 reads:

"One year later, on November 10, 2000, my co-inventors and I filed U.S. [74] Application No. 09/710,102, which was later issued as U.S. Patent No. 6,554,780 (the 780 patent)."

Do you see that sentence?

A. Yes, I can.

MR. RAJANI: I am going to mark as Truckai Exhibit 5 a document that's Bates-labeled HOL-MIN_145183 through 145190.

(Exhibit 5 marked for identification.)

BY MR. RAJANI:

Q. And if you can take a look at it and tell me if you recognize the document.

MS. ELSON: Thank you.

Sorry. This is Exhibit –

MR. RAJANI: 5.

MS. ELSON: 5.

BY MR. RAJANI:

Q. And if it helps you, the page in which I'm interested is the one ending in 186 titled "Assignment."

Have you seen this assignment before?

MS. ELSON: Objection. Form.

THE WITNESS: I'm pretty sure I did, but I'm not – I can't recall. It's been a long time.

///

[75] BY MR. RAJANI:

Q. Does your signature appear on the page ending in 187?

A. Yes, that's my statement. Probably I reviewed it at the time.

Q. Did you sign this assignment in Exhibit 5 under penalty of perjury?

A. Yes.

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: I signed this with my understanding of the declaration, yeah, the assignment.

BY MR. RAJANI:

Q. You signed it knowing that it was under penalty of perjury; right?

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: I'm assigned it as a assigner of the patent, so I'm representing that I'm one of the co-inventor of the patent.

BY MR. RAJANI:

Q. I'm trying to understand what your understanding was when you signed the document. Did you understand that by signing it you were signing [76] it under penalty of perjury?

MS. ELSON: Objection. Form. Legal conclusion.

THE WITNESS: Again, I'm – the only thing I'm saying is that I signed it because I was one of the co-inventor.

MR. RAJANI: I'm going to object as nonresponsive.

BY MR. RAJANI:

Q. What did you do before signing this document?

MS. ELSON: Objection. Form.

THE WITNESS: Could you be more specific?

BY MR. RAJANI:

Q. Before you were ready to sign this assignment, did you do anything to determine whether you would or wouldn't sign the document?

MS. ELSON: Objection. Form.

THE WITNESS: We reviewed the patent.

BY MR. RAJANI:

Q. And at this point it would have been a patent application that you would have reviewed?

A. That's what I meant.

DEPOSITION REPORTER: I'm sorry?

THE WITNESS: That's what I meant.

[77] BY MR. RAJANI:

Q. And did you certify that you reviewed and understood the contents of that application? Right?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, I understood it.

BY MR. RAJANI:

Q. And the application number is listed here on the page ending 186 as application number 09/710,102; right?

MS. ELSON: Objection. Form.

THE WITNESS: That's correct.

BY MR. RAJANI:

Q. Let's go back to – let's go to the first paragraph of the assignment. It has the names of a number of the inventors listed on the first line; right?

A. Correct.

MS. ELSON: Objection. Form.

THE WITNESS: Correct.

BY MR. RAJANI:

Q. And on the next line where it says "Assignors," in all capitals, do you see where it says, "have invented certain new and useful improvements as described and set forth in the below-identified application for United States [78] Letters Patent."

Do you see that part of the sentence?

A. Yes, I can.

Q. And you understood that as part of signing this assignment you attested that you believed that you invented the subject matter described in the application?

A. Co-invented.

Q. Do you still believe your statements in Exhibit 5 to be true today?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Okay. Let's go back to your declaration, which is Exhibit 1.

A. Okay.

Q. Page 1.

A. Page?

Q. Page 1.

All right. Do you see a section heading A titled "The Moisture Transport Prototypes and Patents" towards the bottom of the page?

A. Yes, I can.

Q. And just generally, in this section of your declaration, are you describing your prototyping [79] work at Novacept?

MS. ELSON: Objection. Form.

THE WITNESS: That's what it describes.

BY MR. RAJANI:

Q. And you turned in your lab notebooks when you left Novacept; right?

A. Yes.

Q. Do you still have copies of any documents, like lab notebooks or other documents, reflecting this prototyping work that you did at Novacept?

A. No, I don't.

Q. Is it fair to –

A. Everything I had, I provid- – I gave to the company when I left as an employee.

Q. Is it fair to say that you haven't seen any documents reflecting the prototyping work that you did at Novacept since you left Novacept?

MS. ELSON: Objection. Form.

THE WITNESS: It's – that's a correct assumption.

BY MR. RAJANI:

Q. Let's turn to page 4 of your declaration, paragraph 8. In the last sentence it says:

"I believed at the time (as I still do today) that it is highly undesirable to [80] use more electric current than necessary inside the human body."

Do you see that sentence?

A. Yes, I can see it.

Q. At the time did you have in mind a certain amount of electric current that you considered unsafe in the human body?

MS. ELSON: Objection. Form.

THE WITNESS: There are general guidelines for that, but you want to use as little as is humanly possible.

DEPOSITION REPORTER: "Use" –

THE WITNESS: As little energy as is humanly possible.

BY MR. RAJANI:

Q. Why?

MS. ELSON: Objection. Form.

THE WITNESS: If anything goes wrong, with more energy, you do more damage. So you are trying to minimize the potential damage can cause by, you know, the device.

BY MR. RAJANI:

Q. But did you have in mind any particular threshold of energy that you considered to be unsafe at the time?

[81] MS. ELSON: Objection. Form.

THE WITNESS: Again, the guidance says that, you know, you have to do less than 400 watts per second delivered, so it's a limit, you know, per the FDA, so –

DEPOSITION REPORTER: I need that again. The guidance says that, you know, you have to do per hundred watts per second" –

THE WITNESS: The FDA guidance is 400 watts per second energy delivered or power delivered to the patient. That's a limit set by the FDA. So anything below that is safe. Nevertheless, you want to use as little as is humanly possible. You do less harm in certain cases.

BY MR. RAJANI:

Q. At the time did you have in mind a particular amount of electric current that was necessary to perform ablation?

MS. ELSON: Objection. Form. Vague and ambiguous.

THE WITNESS: Based on the experimentation and product development at Novacept, we came up with the energy requirement to perform the procedure.

DEPOSITION REPORTER: To –

THE WITNESS: Perform the procedure.

[82] BY MR. RAJANI:

Q. Let's stay on page 4 of your declaration, paragraph 8. It's the one that begins, "To summarize."

Do you see that?

A. I'm sorry?

Q. Do you see the paragraph that begins, "To summarize"?

A. Oh, yes.

Q. Okay. In the summary paragraph you're noting that the presence of a moisture layer would – and I'll direct you to iii – "interfere with how the system controlled the depth of ablation."

Do you see that?

A. Yes, I can.

Q. In your view, does the presence of a moisture layer interfere with how the system controls depth of ablation?

MS. ELSON: Objection. Form.

THE WITNESS: The way the NovaSure system, so at the time I meant here very specifically a direct RF device that the electrodes did actively conducting the tissue, yes. So the answer is yes.

///

[83] BY MR. RAJANI:

Q. So the reference to the system –

A. Its a reference to the NovaSure system.

Q. Let's just remind each other not to cut each other off.

A. I'm sorry.

Q. It makes it a lot harder for the reporter.

So the problem regarding depth of ablation occurred because the NovaSure system controlled depth of ablation by monitoring impedence; right?

MS. ELSON: Objection. Form. Vague and ambiguous.

THE WITNESS: Could you repeat that. I mean –

BY MR. RAJANI:

Q. Sure.

A. – you put too many things together there, and –

Q. Sure. I assure you its the fault of the question.

Did the NovaSure system control depth of ablation by monitoring the impedence of the tissue?

MS. ELSON: Objection. Form.

THE WITNESS: It's a partial. We monitor the impedence, but together with the power density [84] and with the moisture transport we control the depth of ablation. If it didn't have moisture transport, it didn't control it.

BY MR. RAJANI:

Q. Are there other ways in which you could monitor or terminate ablation rather than monitoring impedence of the tissue?

MS. ELSON: Objection. Form. Hypothetical.

THE WITNESS: I mean, its been known to the art that people, for example, used temperature sensors in the prior art or other means to see how far the tissue – or just they just used time, depending – dependent on the type of energy delivered. So its very hard to answer just like that.

BY MR. RAJANI:

Q. Was it – strike that.

You mentioned temperature. Is it your understanding that it was possible to terminate the delivery of RF energy when the temperature of the tissue reaches a particular temperature?

MS. ELSON: Objection. Form. Hypothetical.

THE WITNESS: I can't – I want to answer, [85] but I can't because you – it's very vague, so it depends how you doing it.

BY MR. RAJANI:

Q. What would you need to know to determine if you could use temperature to dictate when the delivery of RF energy would stop?

MS. ELSON: Objection. Form. Hypothetical.

THE WITNESS: I mean, it is many different ways, and I – it's been done in the prior art. I mean, they do it in cardiac ablation and other areas. It depends on the very specific procedure and conditions.

So, again, I'm – if you want me to explain how, for example, cardiac ablation works, I can do that; or the way they did liver ablation, I can do that. But, again, it depends, you know, on the particular device. So it's device- and procedure- and condition-dependent.

BY MR. RAJANI:

Q. Did any of the prototypes that you worked on at NovaSure use thermocouple or other temperature sensors to monitor the depth of ablation?

A. Not as I recall. We tried to map, you know, the ablation depth. So, again, your question, [86] it has to be a little bit more specific, you know, in what regard.

Q. Do you recall ever using a temperature sensor or thermocouple to monitor the depth of ablation when you were developing the prototypes at Novacept?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, but we able to only monitor the temperature when we turned the RF off – off, because the RF introduces noise, and you can't measure – you couldn't measure at that time temperature.

BY MR. RAJANI:

Q. So you were trying to measure temperature –

A. But we couldn't in realtime. We couldn't in realtime.

Q. Who did that testing?

MS. ELSON: Objection. Form.

THE WITNESS: I was one of the person who did it. I tried to do that too, but others.

BY MR. RAJANI:

Q. Why were you trying to use temperature – why were you trying to monitor the temperature during the time that RF energy was on?

[87] MS. ELSON: Objection. Form.

THE WITNESS: So during the ablation, could I measure in realtime was the depth of heating –heated zone within the tissue. So I assured that the temperature sensor was inserted into the tissue. It was not on the surface. It was in the tissue in a certain depth.

DEPOSITION REPORTER: I'm sorry. "So during the ablation could I measure in realtime was the depth of heating – heat in zone within the tissues so I assured that the temperature" –

THE WITNESS: So during the ablation, we were not able to measure the temperature below the surface of the tissue, what we try to treat, because of the radio frequency noise is introduced into the radio – into the thermocouple.

BY MR. RAJANI:

Q. Is that when you decided to use the monitor impedence instead?

MS. ELSON: Objection. Form. Mischaracterizes.

THE WITNESS: No. It was a process of development, you know. We tried many things, so . . .

BY MR. RAJANI:

Q. How long would you say that you spent [88] testing the temperature sensor?

MS. ELSON: Objection. Form.

THE WITNESS: I don't remember. It was 20-some – 20 years ago, so . . .

BY MR. RAJANI:

Q. Is it hard to recall something 20 years ago?

MS. ELSON: Objection. Form. Argumentative.

THE WITNESS: You do remember certain things. In some respect, I will not. Precise dates, hours – I mean, I don't think you can expect anyone to remember, you know, how many days, hours, you know, twenty years ago spent on something. We spent time on it.

BY MR. RAJANI:

Q. Let's go to page 12 of your declaration.

Do you see the section heading C in the middle of the page titled The Development of Minerva's Accused Device"?

A. Yes, I can see it.

Q. And is it fair to say that this section of your declaration describes the development of Minerva's EAS? Right?

A. This describes the Minerva PFA, better to [89] say, which is an integral part of the device.

Q. What you mean to say it doesn't describe the entire endometrial ablation system; it more specifically describes the development of Minerva's PFA?

MS. ELSON: Objection. Form.

THE WITNESS: It described the device but more focused on the PFA.

BY MR. RAJANI:

Q. Let's go to page 14 of your declaration, paragraph – actually, let's go to page 15, paragraph 41. You write:

"To summarize, my team and I had to perform numerous experiments during the development phases described above to eventually arrive at the final, working design of Minerva's PFA."

Do you see that?

A. Yes, I can.

Q. So the numerous experiments that you're referring to in this sentence refers to the development of the Minerva PFA; right?

A. Minerva PFA and – yes.

Q. These aren't the experiments that were necessary to create the NovaSure prototypes; right?

[90] MS. ELSON: Objection. Form.

THE WITNESS: Part – part of the NovaSure device. I mean, this is the – the primary – the primary experiments were to develop the plasma formation within the Minerva device.

DEPOSITION REPORTER: "Within the" –

THE WITNESS: Plasma formation.

DEPOSITION REPORTER: "Within the" -

THE WITNESS: Within the – the Minerva PFA. Plasma formation array.

BY MR. RAJANI:

Q. So these were – these were not the primary experiments that were needed to develop the NovaSur device; right?

MS. ELSON: Objection. Form.

THE WITNESS: The – again, the primary experiments, you know, started, way back, you know, when we were looking at the orthopedic device, and,

again, we just realized that, you know, this is something very usable in other fields. So it's a long process. Many things have to be resolved. So if, you know, you be – if you ask more specific, you know, I can tell you what you're looking for.

BY MR. RAJANI:

Q. Yeah. So let's go back to paragraph 41. [91] In the first line you are referring to performing numerous experiments. Do you see that?

A. Uh-huh.

Q. Are those experiments that you're describing related to the development of Minerva's PFA or the Novacept device?

A. This is –

MS. ELSON: Objection. Form.

THE WITNESS: This is Minerva device. Did I say Novacept?

BY MR. RAJANI:

Q. I couldn't quite tell, but you've clarified. Thank you.

So, to be clear, you don't believe that these are the experiments that were necessary to create NovaSure; right?

MS. ELSON: Objection. Form.

THE WITNESS: Just could you repeat it one more time.

BY MR. RAJANI:

Q. Yeah.

A. So these are –

Q. The numerous experiments that you referenced in paragraph 41 –

A. Yes.

[92] Q. – those are not the experiments that you believed were necessary to create the NovaSure prototypes; right?

A. These experiments that perform specifically for the Minerva device.

Q. I see. Let's go to page 23 of your declaration. I'll direct you to paragraph 60.

A. 21?

Q. Page 23, paragraph 60. The second sentence of paragraph 60 reads, "Fully aware that the '183 patent" –

A. I'm sorry. Could I have it one more time.

Q. Second sentence –

A. Uh-huh.

Q. – reads:

"Fully aware that the '183 patent claims the use of a 'pressure sensor' as its solution for monitoring for perforations in the uterus, we at Minerva decided to develop our own solution based on the use of a flow meter."

You see that; right?

A. Yes, I can.

Q. What do you mean when you say "fully aware" in this sentence?

[93] A. Since I was a co-inventor, I was aware of the existence of the NovaSure patent or Novacept at the time in the company.

Q. So the sentence said that, you know, "fully aware of the '183 patent"; the second half, it says, "we at Minerva decided to develop our own solution."

Did Minerva decide to use what you referred to here as a flow meter because the '183 patent recited a pressure sensor?

MS. ELSON: Objection. Form.

THE WITNESS: No. We were aware of the problems using the pressure sensor. There is – there was lots of issues with the pressure sensor, and those issues, you know, created lots of problems in the field – you know, failed treatments, etc., etc., so you know, to use –

DEPOSITION REPORTER: I'm sorry. "Lots of problems in the field."

THE WITNESS: In the field –

DEPOSITION REPORTER: And then –

THE WITNESS: – with physicians where they – its called a failed treatment. They weren't able to treat the patient because the pressure sensor false- – falsely detected a perforation, and there was no perforation.

[94] BY MR. RAJANI:

Q. So Minerva decided to develop its own solution using what you call a "flow meter" because of problems it was seeing in the field?

MS. ELSON: Objection. Form.

THE WITNESS: Because we were aware of the shortcomings of other devices which is using pressure sensor and, you know, our goal was to develop a new technology which is more sensitive and provides the – the user, the physician, a better method detecting perforation.

BY MR. RAJANI:

Q. And so Minerva was fully aware that the '183 patent claimed a pressure sensor; right?

MS. ELSON: Objection. Form.

THE WITNESS: I was aware and my co-workers, yes.

BY MR. RAJANI:

Q. How were your co-workers aware of that?

A. Because I described to them the issues which is in the field at the time, you know, with the – the NovaSure product that, you know, many times they are unable to repair from the ablation because the pressure sensor faultly declares that you have a perforation. And one of the goals and [95] what they set is that we have to come up with a better, more reliable method to detect perforation, which is very important.

Q. Let's turn to page 6 of your declaration, paragraph 12. And the last sentence of paragraph 12 reads, Our refined prototype" –

DEPOSITION REPORTER: I'm sorry. Can you start that again.

BY MR. RAJANI:

Q. "Our refined prototype, on which the disclosures in the MT Provisional and the '072 application were based, used a handle with distal and proximal grips pivotally attached at a pivot point rather than the earlier syringe-like handle."

You wrote this sentence?

A. Yes.

Q. Did you use the phrase "pivotally attached at a pivot point" when you were designing this prototype?

MS. ELSON: Objection. Form.

THE WITNESS: I mean, that was the device we used. Actually, there was lots of issue with that one too because the size of handle we ended up [96] with, it was very uncomfortable for the female users.

MR. RAJANI: I am going to object as nonresponsive.

BY MR. RAJANI:

Q. My question is: Did you use the phrase "pivotally attached at a pivot point" at the time when you were designing the prototype?

MS. ELSON: Objection. Form.

THE WITNESS: At the time when I designed a NovaSure device, I don't know how I called it. But if I describe it now, that's the way I would describe it in technical terms.

BY MR. RAJANI:

Q. Who was designing the handle, the NovaSure handle, at the time?

MS. ELSON: Objection. Form.

THE WITNESS: It's – it was a number of us.

BY MR. RAJANI:

Q. Who?

A. Russ Sampson, myself, Stephanie Squarcia. I mean, there are a number of people who contributed.

Q. Do you see the phrase in the last line that [97] I just read referring to "the earlier syringe-like handle"?

A. Yes.

Q. Is it fair to say that the early NovaSure prototype used a syringe-like handle to open and close the applicator head?

A. No.

Q. So what is this reference to "the earlier syringe-like handle"?

A. We made a conceptual design, which actually was put into the patent too. It's just a potential embodiment, but it never had the force, you know, to open or close the device. So it was a conceptual version which we made actual prototype of, but it was unfunctional. And on that one, that was only me. Nobody else.

Q. And do you consider that – strike that. What do you mean by "conceptual version"? As opposed to what?

A. I used to go and try to raise money to venture capital companies, so, you know, we had to do something, and the easiest version was, you know to modify the existing syringe-type device. So we didn't have the funds to, you know, design very quickly,. mold, et cetera. so it was a svrinae-tvoe

[99] MS. ELSON: Objection. Form.

THE WITNESS: Our invention really which we were going for is the moisture transport. Any handle could do it.

MR. RAJANI: I think we need to change the media, so let's go ahead and take a break.

THE VIDEOGRAPHER: This now marks the end of disc labeled No. 1 of the video deposition of Csaba Truckai. We are now going off the record. The time is 2:57.

(Off the record.)

THE VIDEOGRAPHER: This now marks the beginning of disc labeled No. 2 in the video deposition – deposition of Csaba Truckai. We are now going back on the record, and the time is 3:07.

BY MR. RAJANI:

Q. Mr. Truckai, you understand that you're still under oath?

A. Yes, I do.

Q. When we just broke, we were speaking about some of the early designs involving a syringe-like handle. Do you recall that?

MS. ELSON: Objection. Form.

THE WITNESS: Yes, we talked about that.

MR. RAJANI: Let me mark as Truckai [98] device which we took and we modified. But it was never functional.

Q. So do you consider the earlier syringe-like handle to be part of what you invented?

MS. ELSON: Objection. Form.

THE WITNESS: The handle is less important in the early invention. The early invention, what we had is a moisture transport. It's not talking about – really about the handle. The handle does- – it's not important.

MR. RAJANI: I'm going to object as nonresponsive.

BY MR. RAJANI:

Q. My question is whether you considered the earlier – strike that.

Did you consider the conceptual embodiment with the syringe-like handle to be one of your inventions?

MS. ELSON: Objection. Form. Asked and answered.

THE WITNESS: I mean, we never considered this an invention, the handle.

BY MR. RAJANI:

Q. Okay. You never considered this to be a part of the invention? [100] Exhibit 6 a copy of the '348 patent.

(Exhibit 6 marked for identification.)

BY MR. RAJANI:

Q. You're familiar with this document?

A. I've seen this document.

Q. Are you a named inventor on this patent?

A. My name is on the patent.

Q. Can you turn to the drawings that start about five pages in. The drawing has Figure 1 and Figure 2 side by side. Do you see those?

A. Yes, I can.

Q. What type of handle is depicted in Figures 1 and 2?

A. This drawing is a direct representation of the syringe type of handle.

Q. And was it your testimony that you did try to build this type of handle?

MS. ELSON: Objection. Form.

THE WITNESS: We built it, but it never really performed.

BY MR. RAJANI:

Q. When you say "it never really performed," what do you mean by that?

A. It wasn't really able to perform, you know, in a device. You know, it – you know, it worked as [101] a mockup device at the time. And the handle for us wasn't an important part of the invention. The invention is the moisture transport array, so we weren't really focusing on the handle. It was just a embodiment. It could have been five different types of embodiment.

MR. RAJANI: I'm going to object to the last portion of your response as nonresponsive.

BY MR. RAJANI:

Q. Do you consider this to be – strike that.

Do you consider the mockup that you made with the syringe-like handle to be a prototype of the NovaSure device?

MS. ELSON: Objection. Form.

THE WITNESS: No.

BY MR. RAJANI:

Q. Why not?

A. Because we never built one like this which functioned.

Q. So the only prototypes that you are including are the ones that have which function?

A. Which perform the moisture transport function.

Q. So if there was an earlier prototype you made that didn't perform a particular type of [102] moisture transport, you don't consider that to be a prototype of

the NovaSure device; right? MS. ELSON: Objection. Form.

THE WITNESS: So for you to understand what we had at the time, I mean – repeat, please, one more time your question. I'm trying to answer it.

BY MR. RAJANI:

Q. I'm trying to understand what you're defining as a prototype. And earlier you mentioned that you don't consider the syringe-type handle -¬the mockup that you made with the syringe-type handle to be a prototype of the NovaSure device; is that fair?

MS. ELSON: Objection. Form.

THE WITNESS: No, because we didn't care about the handle. We really didn't focus on the handle at all. We didn't even have a handle. All the prototypes we built, you know, that was little screws and nuts which, you know, moved the array open. That's what we used. We didn't have a handle.

BY MR. RAJANI:

Q. Let's turn to Figure 22 of the '348 patent. Figure 22 depicts a different type of handle; right?

[103] A. Yes.

Q. And, in your view, is this the pivotally attached handle?

A. Yes.

Q. Why?

A. Point –

MS. ELSON: Objection. Form.

THE WITNESS: Sorry. Point 166 is the pivot point.

BY MR. RAJANI:

Q. Does Minerva's handle have a proximal and a distal handle too?

MS. ELSON: Objection. Form.

THE WITNESS: Could you –

MS. ELSON: Vague and ambiguous.

THE WITNESS: Could you define what's proximal and distal?

BY MR. RAJANI:

Q. Do you understand what a proximal and a distal handle are?

MS. ELSON: Objection. Form. Vague and ambiguous.

THE WITNESS: In the Minerva device or in the NovaSure device or –

///

[104] BY MR. RAJANI:

Q. Do you – I'll clarify.

A. I'm sorry.

Q. I'll clarify.

Do you understand what the terms "distal" and "proximal" grips mean?

A. What my understanding is, proximal is closer to me; distal is farther from me. But, you know, since, you know, so many different types of handles out there in the world, you know, I cannot give you more precise information besides – I know the words, but I don't know what you're referring to.

Q. Does Minerva's EAS handpiece have grips?

MS. ELSON: Objection. Form.

THE WITNESS: It has members that you can hold with your hand.

BY MR. RAJANI:

Q. And are there two grips?

MS. ELSON: Same objection.

THE WITNESS: One moving, one stationary.

BY MR. RAJANI:

Q. Which one do you consider to be stationary?

MS. ELSON: Objection. Form.

THE WITNESS: The one which, you know,

* * *

[129] describing very well, you know, how our UIT systems work, so I think this has important relevant information about it.

BY MR. RAJANI:

Q. Can you go to the page that ends in the Bates number 5310.

A. Which one? I'm sorry. What number?

Q. 531, the last three digits.

Do you see a comment in the margin?

A. "This need to be modified for real system simplified diagram."

Q. Did you author that comment?

A. I'm not sure.

Q. Do you know who did?

A. I'm not sure.

Q. Who first provided a copy of Exhibit 7 to you?

MS. ELSON: Object- – I'm going to instruct not to answer. Privileged.

BY MR. RAJANI:

Q. Who first – strike that.

Do you specifically recall receiving this document in 2009?

A. No, yes. But if you asked me, you know, a couple of years ago, I wouldn't be able to [130] remember, so...

Q. I'm not sure I understood your answer. Let me ask it again.

Do you specifically recall receiving this document in 2009?

MS. ELSON: Objection. Form.

THE WITNESS: I remember that – I remember that I received it, but I didn't remember precisely the time until I looked.

BY MR. RAJANI:

Q. Do you specifically recall discussing this document with anyone in 2009?

MS. ELSON: Assuming you can answer that without revealing attorney-client communications, you can answer that question.

THE WITNESS: Mr. Akos Toth.

BY MR. RAJANI:

Q. And you specifically remember discussing this document with Mr. Toth in 2009?

A. No, I don't remember.

Q. How do you remember you discussed it with him, then?

A. Because anything got to do with the UIT, it's – it was his invention, you know, his work platform, and he, you know, did actly [verbatim].

[131] DEPOSITION REPORTER: It was his what platform?

THE WITNESS: His invention.

DEPOSITION REPORTER: "His" –

THE WITNESS: That was his work.

BY MR. RAJANI:

Q. So you don't remember specifically discussing this document with Mr. Toth; right?

A. This document, it was discussed at the time with multiple people, so I'm pretty sure it was more than just Akos Toth. The entire R&D team, you know, reviewed this. This is – this is a document not for one person. But for fact, since he was there, the primary inventor on the UIT, you know – for fact I can tell you that he was involved with it.

He generated, you know, the diagram in this exhibit.

MR. RAJANI: I'm going to mark as Truckai Exhibit 8 a document –

MS. ELSON: 8 or 9?

MR. RAJANI: 8. Did I – I think it's 8. The last one was 7.

MS. ELSON: Oh, okay.

MR. RAJANI: It's a document labeled MSI0029738 through 297551.

(Exhibit 8 marked for identification.)

[132] BY MR. RAJANI:

Q. Are you the author of Exhibit 8?

MS. ELSON: Objection. Form.

THE WITNESS: Nope.

BY MR. RAJANI:

Q. Was Exhibit 8 produced from your files?

MS. ELSON: Objection. Form.

And if the answer would reveal any attorney-client privilege, I instruct you not to answer.

THE WITNESS: I can't answer. I will take my counsel advice on that.

BY MR. RAJANI:

Q. You're telling me that whether this came from your files is privileged?

MS. ELSON: That wasn't the question.

BY MR. RAJANI:

Q. Was Exhibit 8 produced from your files?

MS. ELSON: To the extent you are asking about production that involves attorney involvement, I instruct him not to answer.

THE WITNESS: So on that level I am taking my counsel advice.

MR. RAJANI: And your understanding is that if this document, Counsel, was produced from his [133] files, because it was in a production, it's all of a sudden privileged, whether or not it came from his files?

MS. ELSON: I'm not going to argue with you, Counsel.

MR. RAJANI: I'm not trying to argue. I'm trying to find the basis of these objections, which are so off-base, but . . .

MS. ELSON: That's your view.

BY MR. RAJANI:

Q. Who authored Exhibit 8?

A. As you can see, the first author, X1, it's Akos Toth. It says, "Initial Release." Then you can see the – the revisions, so you can see the first revision was Akos Toth, and then X4 is Ron Hundertmark.

Q. You are reading from the first page of this exhibit; right?

A. That's right. It says, "Change Record."

Q. And those names are under the column "Responsible Person"; right?

A. That's correct.

Q. Are you assuming the person that's responsible is also the author of the document? A. Because of the quality system that's [134] required. That's the fact.

DEPOSITION REPORTER: Because of the what system?

THE WITNESS: The quality system. The person who responsible for the revision is the author of the document.

BY MR. RAJANI:

Q. Do you recall – prior to your preparing for this declaration, did you have an independent memory of this particular document?

MS. ELSON: Objection. Form.

THE WITNESS: I can tell you every single document was sent to me, so, yes, product specification is a very important document. And as you can see, there are multiple revisions, so it's not just one document. This is the fourth revision of that document.

MR. RAJANI: I'm going to object as nonresponsive.

BY MR. RAJANI:

Q. Let me try and phrase it a different way.

Before you started preparing the declaration as Exhibit 1, did you have an independent memory of this particular document that's marked as Exhibit 8?

MS. ELSON: Objection. Form. Asked and [135] answered.

THE WITNESS: Again, the only thing I can tell you, that every single document which was product – was product-specification-related was -¬ended up at me. And this is the fourth edition, and I'm pretty sure there are other editions, you know, on that, so...

BY MR. RAJANI:

Q. Did you see any of the other editions when you were looking through your email to prepare for your declaration?

MS. ELSON: Objection. Form.

THE WITNESS: I have to look again to be sure.

BY MR. RAJANI:

Q. Do you recall when you were looking through it whether you saw any other versions, just sitting here today?

MS. ELSON: Same objection.

THE WITNESS: I have to look and confirm. There are a number of editions. So, you know, you asking me which edition you talking about it, is very difficult for me to say if, you know, X1, X- -¬yeah, as you can see.

///

[136] BY MR. RAJAN I :

Q. Do you recall seeing multiple versions of this document when you were looking through your emails to prepare for this declaration?

MS. ELSON: Objection. Form.

THE WITNESS: Yes.

BY MR. RAJANI:

Q. Can you go to the page ending in 547 in this document. Do you know who authored the redlines on that page?

A. This – this entire document, it was altered by Ron Hundertmark.

Q. Do – is it your understanding that Mr. Hundertmark is the one who drafted the redlines, made the changes that are reflected?

A. So the way you have to read this document, it says at the bottom here its X4. Then you can see here – on the revision X4 you can see it was done by Ron Hundertmark, and then you can see the changes, which is described: various, format, clarity, edit, additional –

DEPOSITION REPORTER: "Which is described" –

THE WITNESS: Which are described under the "Description of Change." It's on the front page.

* * *

[173] DEPOSITION REPORTER: Oh.

BY MR. RAJANI:

Q. So in paragraph 29 you say:

"A relatively small amount of RF current (as compared to the NovaSure) flows between the single internal electrode and the second external 'return' electrode on the exterior of the PFA."

Do you – do you believe that statement is accurate?

A. It is accurate.

Q. Okay. Is that the only direction in which the RF current can flow in the Minerva EAS?

A. No.

Q. And I can be a little bit more specific.

Is there any RF energy being sent in the other direction from the external electrode through – to the internal electrode?

A. This is radio frequency. Just, you know, the polarities changing all the time.

Q. Is that a function of it being an alternating current?

A. It's a function of an alternating current.

Q. So the internal electrode could also serve as the return electrode?

[174] MS. ELSON: Objection. Form.

THE WITNESS: I mean, you can use terms, but we are talking about two electrodes, period. One is on the outside, and one is on the inside, the polarity of the electrodes alternating.

BY MR. RAJANI:

Q. And are you aware that the parties in this case are disputing what the term "pressure sensor" means?

MS. ELSON: Objection. Form.

Let me instruct – if you can exclude any –

MR. RAJANI: I can – let me withdraw the question.

MS. ELSON: Okay.

BY MR. RAJANI:

Q. I'm just asking for a "yes" or no as to whether you are aware that the parties have proposed competing constructions of what the term "pressure sensor" means.

MS. ELSON: And objection. Form. Legal conclusion.

You can answer that question, but just I caution you not to reveal the substance of any attorney-client communication.

[175] THE WITNESS: I don't know precisely what the argument – the legal argument is.

BY MR. RAJANI:

Q. Let's go to paragraph 57 of your declaration. The last sentence of paragraph 57 reads:

"In 1999, I personally understood a pressure sensor to be a device that directly detects a force per unit area at its input."

What do you mean by "directly detects a force per unit"?

MS. ELSON: I'm sorry.

MR. RAJANI: Last sentence of paragraph 57.

MS. ELSON: I apologize. Go ahead.

BY MR. RAJANI:

Q. What do you mean in that sentence by "directly detects a force per unit area"?

A. It means that the pressure you apply to the pressure sensor measure the pressure.

Q. That's what you mean by "directly detects a force"?

A. Yes.

Q. How do you recall what you personally understood a pressure sensor to be in 1999?

[176] A. How do – I'm sorry.

Q. How did you – how did you remember what you personally understood a pressure sensor to mean in 1999?

A. Before 1999 – after '99 I used pressure sensor for many applications. I know what's pressure and sensor is. It's very common in the medical US industry to measure pressure.

Q. Let's go to paragraph 55 of your declaration. The last sentence reads:

"That device was only a pressure sensor consistent with my understanding of a pressure sensor (. . . a device that detects a force per unit area at its input and outputs a corresponding value)."

Is this consistent with your understanding of what a pressure sensor was in 1999?

MS. ELSON: Objection. Form.

THE WITNESS: That's correct. And that's what I referred before to.

BY MR. RAJANI:

Q. This reference in paragraph 55 doesn't refer to directly detecting a force per unit area, does it?

A. No, but its stating that its a device

* * *

[201] I, JANIS JENNINGS, CSR No. 3942, Certified Shorthand Reporter, certify:

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was duly sworn by me;

That the testimony of the witness, the questions propounded, and all objections and statements made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing pages contain a full, true and accurate record of all proceedings and testimony.

Pursuant to F.R.C.P. 30(e) (2) before completion of the proceedings, review of the transcript [ ] was [X] was not requested.

I further certify that I am not a relative or employee of any attorney of the parties, nor financially interested in the action.

I declare under penalty of perjury under the laws of California that the foregoing is true and correct.

Dated this 2nd day of November 2017.

/s/ Janis Jennings
JANIS JENNINGS, CSR NO. 3942
CLR, CCRR

[202] DEPOSITION ERRATA SHEET

Esquire Litigation Services Assignment No. J0670065
Case Caption: HOLOGIC, INC., et al., vs. MINERVA SURGICAL, INC.

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the __ day of _____, 20__.

_____

CSABA TRUCKAI

[202] DEPOSITION ERRATA SHEET

Esquire Litigation Services Assignment No. J0670065
Case Caption: HOLOGIC, INC., et al., vs. MINERVA SURGICAL, INC.

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the 07 day of November, 2017.

/s/ Csaba Truckai
CSABA TRUCKAI

[203] DEPOSITION ERRATA SHEET

Page No. 114 Line No. 23 Change to: specifically talk about the flow control section

Reason for change: correct sentence

Page No. __ Line No. __ Change to: _____

Reason for change:

Page No. __ Line No. __ Change to: _____

Reason for change:

Page No. __ Line No. __ Change to: _____

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Reason for change:

Page No. __ Line No. __ Change to: _____

Reason for change:

SIGNATURE: _____ DATE: _____

Csaba Truckai

From: Michael Regan
Sent: Sunday, January 30, 2011 3:52 PM
To: Anderson, Ted L
Cc: Mary Edwards; Csaba Truckai; Eugene Skalnyi
Subject: RE: cMinerva Case Update to MAB

Hi Dr Anderson:

Thanks for your comments on our peri-hysterectomy series. The hysterectomy is typically done just following the ablation treatment. The uterus is sent to pathology within the hour. We have not done any 2-4 week post treatment hysterectomy. Discussions to date with FDA indicate that we won't he required to do "delayed hysterectomy' cases. Regarding the patent position, we have been closely working with counsel on this matter since the inception of the company and will continue this approach on our design choices.

I appreciate your insights and the review of our clinical protocol which you provided in a separate email.

Take Care Mike

From: Anderson, Ted L [mailto:ted.anderson@Vanderbilt.Edu]
Sent: Thursday, January 27, 2011 7:55 AM
To: Michael Regan
Subject: RE: Minerva Case Update to MAB

looks good.

How long after treatment is the hysterectomy done?

Have you looked at hysterectomy about 2-4 weeks after treatment? There is going to be further tissue devitalization after the initial burn and it would be good to examine at what that looks like.

I have one sort of global question. I envision major "patent infringement" disputes for this device vs Novasure. How is this being dealt with or how do you plan you will be able to deal with it?

Ted L. Anderson, MD, PhD, FACOG, FACS
Director, Division of Gynecology and Gynecologic Surgery
Department of Obstetrics and Gynecology
Vanderbilt University Medical Center
Nashville, TN 37232
tel: 615-343-6710
fax: 615-343-8881
ted.anderson@vanderbi lt.edu

From: Michael Regan [michaelr@minervasurgical.com]
Sent: Wednesday, January 26, 2011 7:01 PM
To: Andrew Brill; Anderson, Ted L; Donald Galen MD (drgalen@drgalen.com); Adolf Gallinat; Amy Garcia; Richard Gimpelson MD (epabernathy@hotmail.com)
Cc: Csaba Truckai; Mary Edwards; Carol Anne Yarbrough; Dominique Filloux
Subject: Minerva Case Update to MAB

Dear Drs. Brill, Anderson, Galen, Galinat, Garcia, and Gimpleson

We just want to update you on our latest series of peri-hysterectomy cases last week. We are happy to report that we completed 4 additional cases in Hungary at two sites. This brings the cumulative peri-hysterectomy experience to 7 cases. We hope to have the formal pathology report within the next two weeks. In the meantime, the attached files and gross pathology observations noted below give an indication of the results. We were fortunate to have Dr Gallinat proctor these cases which helped tremendously with the new user learning curve.

Procedural observations and potential future improvements:

-perforation detection system works well if we can keep the blood out of the tubing (we need to install a small blood capturing container)

-we are investigating methods to minimize tip profile during insertion through the cervix

-auto inflation in device vs in controller may be preferred because device can be removed multiple times in a procedure

-length setup is cumbersome to know where the device is set (investigating a number in “window” to make reading the number easier)

-a suggestion was made to use “dot scale” for feedback on cornu to cornu measurement additionally it might be helpful to increase the resolution of the “reading” scale

-we are looking into software to prompt the user to reposition device if power is below 40W within the first 1-20 seconds of the ablation

Pathology Pictures and gross measurements:

D103

- Highest serosal temp was 36.72 (range 33.98 – 36.72)
- AnteriorTC came loose and did not record temp appropriately
- Closest distance of thermal injury to serosa at right cornu 15.5mm
- Depth of thermal injury (all maximum measurements)
    1. Right cornu anterior – 4.9mm
    2. Right cornu posterior – 4.5mm
    3. Lt cornu anterior – 4.9mm
    4. Lt cornu posterior – 4.3mm
    5. Fundus – 5.0mm
    6. Anterior Right Corpus – 5.0mm
    7. Anterior Left Corpus – 4.3mm
    8. Posterior Right Corpus – 4.1mm
    9. Posterior Left Corpus – 3.8mm

10. Anterior LUS – 4.2mm
11. Posterior LUS – 3.6mm
12. Right Corpus sidewall – 4.1mm
13. Left Corpus side wall – 3.9mnn

From: Dave Clapper
Sent: Tuesday, November 10, 2015 6:10 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Thanks. And by the way, Hologic filed a Complaint for Patent Infringement (lawsuit) on Friday at 5 pm. I can give you the details later. We anticipated something along these lines, and have been working on a response with an IP litigation group for the last 6 months. Our response is "In the can" so to speak. More later.

Dave Clapper
President and CEO
Minerva Surgical

From: <Glaser>, Erik Glaser <erik.glaser@smith-nephew.com>
Date: Tuesday, November 10, 2015 5:09 PM
To: Dave Clapper <daveclapper@minervasurgical.com>
Subject: RE: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Ahh ..yes . . . that's our code word . . . access code 3160290 . . . 1.888.858.6043

From: Dave Clapper [mailto:daveclapper@minervasurgical.com]
Sent: Tuesday, November 10, 2015 8:07 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Thank you. Two quick things: Is Athena interchangeable with Minerva. Two, can you provide a dial-in #\pass code for the call? Couple of our people will be calling in remotely.

Dave

Sent from my iPhone

On Nov 10, 2015, at 3:15 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Dave . . . wanted to send along some questions to help guide tomorrow's call

- ? Why is there a contraindication of hysteroscopic myomectomy prior to the Minerva procedure?
- ? Why are there variations in QOL results between Athena Single Arm and Pivotal studies?
- ? We've reviewed AEs across both Minerva and NovaSure . . . why are there difference in AE data? Let's review the nature and classification of the AEs

These will naturally lead into other discussion points but wanted to give you preliminary view of what the team is thinking

Look forward to the call Erik

From: Dave Clapper [mailto:daveclapper®minervasurgical.com]
Sent: Wednesday, November 04, 2015 4:10 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Ok. I think we have this worked out. Eugene moved his flight back to 5 pm eastern, which should give us plenty of time. How does that sound?

Dave Clapper
President and CEO
Minerva Surgical

From: <Glaser>, Erik Glaser <erik.glaser@smith-nephew.com>
Date: Wednesday, November 4, 2015 9:49 AM
To: Dave Clapper <daveclapper@minervasurgical.com>
Subject: RE: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

I am thinking that we should move the call from next week for the convenience of everyone . . . our CMO is completely out of pocket until 2 pm et and several people are out next Friday.

So maybe at AAGL? I know Mira will have a suite that should hold up to 8 . . . I think she'll be there with 3 of her team . . . sounds like up to 3-4 from the Minerva team? Or we wait until after AAGL

From: Dave Clapper [mailto:daveclapperminervasurgical.com]
Sent: Wednesday, November 04, 2015 12:45 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Any amount of time we can move the meeting up, even 15 minutes will be valuable.

Sent from my iPhone

On Nov 4, 2015, at 8:32 AM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Dave . . . trying to figure out a way to make this work on the 11t" . . . our CMO can't make 12 pm et (he's one of the folks in Europe)

If we stick with 2 pm et on the 11th . . . and get Dr. Skalnyi for-30 minutes . . . will he be in transit to the airport? In other words, probably not the best environment for a call?

From: Dave Clapper [mailto:daveclapper@minervasurgical.com]
Sent: Tuesday, November 03, 2015 9:38 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

It will work, however Dr Skalnyi has a flight at 2:38, so well only have him for 25 minutes or so.

Sent from my iPhone

On Nov 3, 2015, at 7:13 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Appreciate the follow up. . .any way to push the 2 pm et slot? I know there's a lot to line up. . .I should be able to get everyone at 2

Sent from my iPhone

On Nov 3, 2015, at 7:35 PM, Dave Clapper <daveclapper@minervasurgical.com> wrote:

Just heard back from the entire Minerva team. Noon eastern time will allow all of us to be on the call for at least an hour. Would this work?

Sent from my iPhone

On Nov 3, 2015, at 1:01 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Thanks Dave . . . let's tentatively book 2 pm eastern time on the 11th . . . I'm still checking calendars here . . . some folks are in Europe and want to make sure the time zones are accurate!

From: Dave Clapper [mailto:daveclapperminervasurgical.co m]
Sent: Tuesday, November 03, 2015 1:59 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

Hi Erik. I'm catching a flight from DC back to the west coast today.

2pm Eastern on the 11th works.

I'll double check on the AE lists tomorrow when I'm back in the office. I'm 99% sure that we eliminated Attachment 1. All of the AE's are listed in the charts or narrative that you have in the report. Virtually all

AE's following Ablations occur within the first 30 days and most in the first 24 hours. I'll recheck tomorrow.

Depending on your list of questions, I'm anticipating that I will be on the call, plus VP Med Affairs - Eugene Skalnyi MD, CRO - Jan McComb PhD, and possibly VP's of Ops and RD.

We don't have a rep in Boston yet, so I'm not planning a visit there anytime soon.

Dave

Sent from my iPhone

On Nov 3, 2015, at 10:19 AM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

Thanks Dave . . . please see below

- ? I'm looking into the 11th for potential times for management call . . . would 2 pm et work for you/your team? I'm still confirming internal schedules but should know shortly . . . also wanted to confirm who from your team would participate . . . assume CMO and head of clinical to participate? Anyone else (you of course)
- ? Unfortunately, I won't be at AAGL due to travel conflicts
- ? Wanted to get back to you on your funding proposal . . . it sounds potentially intriguing but obviously the devil is in the details . . . want to try and catch up on that after AAGL? Are you potentially in Boston in the near future? Would be great to discuss F2F

Lastly, a couple follow on questions regarding the 1 yr. pivotal report

? Bottom of page 22 and top of page 23 . . . there is a reference to an Attachment 1 (containing listing of AEs) . . . we can't seem to find the attachment 1 . . . did we miss it?

? Reference table VII.B.2. . . it shows post-op AEs @ 4 weeks . . . do you also have AEs at 1 year? Did we perhaps miss the 1 year AE data?

-----Original Message----

From: Dave Clapper [mailto:daveclapper@minervasurgical.com]
Sent: Monday, November 02, 2015 4:54 PM
To: Glaser, Erik
Subject: Re: Confidential "DRAFT" ¬Minerva Pivotal Study One Year Report

The 11th would be best. We could meet at AAGL. Will you be attending anyway? We have several other meetings at AAGL which is par for the course, so I'm not concerned about that. Let me know if anytime in the 11th could possible work. If not, possibly early on the 13th, like 10 am eastern might work.

Sent from my iPhone

> On Nov 2, 2015, at 3:46 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

>

>OK . . . let me see about schedules . . . would it make sense to connect at

AAGL? Would need to find a suitable location that would not raise eye brows.

>-----Original Message------

>From: Dave Clapper [mailto:daveclapper@minervasurgical.com]

>Sent: Monday, November 02, 2015 2:17 PM
>To: Glaser, Erik
>Subject: Re: Confidential "DRAFT" - Minerva Pivotal Study One Year Report

> Hi Erik. The 12 or 13th wont work. And AAGL is the next week, 16, 17, & 18. Yikes!! Any chance of making something work on the 11th??

> Sent from my iPhone

>>On Nov 2, 2015, at 1:31 PM, Glaser, Erik <Erik.Glaser@smith-nephew.com> wrote:

>>

>>Dave,

>>

>>Waned to follow up regarding management call. Unfortunately, due to some travel conflicts, I can't get our team together until next week . . . so could you suggest some convenient dates/times for late next week (12th or 13th) and into the week of the 16th for a management call with your team?

>>

>>I figure an hour should be good? We'll prepare a list of questions to send to you beforehand in preparation to run the call efficiently.

>>

>>Many thanks for your help.

>>Best,

>>

>>Erik

>>

>>-----Original Message-----

>>From: Dave Clapper
[mailto:daveclapper@minervasurgical.com]
>>Sent: Wednesday, October 28, 2015 9:40 PM
>>To: Glaser, Erik
>>Subject: Confidential “DRAFT” - Minerva Pivotal Study One Year Report

>>

>>Erik, attached please find a Confidential “DRAFT” copy of the Minerva Pivotal Study One Year Report. I wanted to get this over to your team for review, while we are still triple checking the data, running statistical significance analysis, and proof reading - proof reading - proof reading! There will very likely be some minor changes and additions to this report before we send it into the FDA. Happy reading, and I hope your team likes the data as much as we do!!

>>Let me know if you have any questions.

>>Dave

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

EXHIBIT 1
JOINT STATEMENT OF UNCONTESTED FACTS

I. PARTIES

1. Plaintiff Hologic, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752.

2. Plaintiff Cytyc Surgical Products, LLC ("Cytyc") (together with Hologic, Inc., "Hologic") is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Cytyc is a wholly-owned subsidiary of Hologic, Inc.

3. Defendant Minerva Surgical, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

II. PATENTS-IN-SUIT

A. U.S. Patent No. 6,872,183 ("the '183 Patent")

4. The '183 Patent is entitled "System and Method for Detecting Perforations in a Body Cavity."

5. The '183 Patent was issued by the United States Patent and Trademark Office ("USPTO") on March 29, 2005.

6. The '183 Patent expires on November 10, 2020.

7. The '183 Patent claims priority to Provisional Application No. 60/164,482, filed November 10, 1999 (i.e., the '183 Priority Date). Original Utility Application No. 09/710,102, filed November 10, 2000, issued as U.S. Patent No. 6,554,780 ("the '780 Patent"). Application No. 10/400,823, filed March 27, 2003, was a continuation of Application No. 09/710,102, and issued as U.S. Patent No. 6,743,184 ("the '184 Patent"). Application No. 10/852,684, filed May 24, 2004, was a continuation of Application No. 10/400,823, and issued as U.S. Patent No. 6,872,183 ("the '183 Patent"). The '780, '184, and '183 Patents all share a common specification. Only the claims of each are different.

8. Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller are the named inventors of the '183 Patent.

9. Hologic, Inc. is the owner by assignment of the '183 Patent.

10. Hologic, Inc. acquired the '183 Patent from Cytyc on January 15, 2016.

11. Csaba Truckai assigned his interest in the '183 Patent to Novacept, Inc. on February 9, 2001.

12. In February 2001, Csaba Truckai assigned his interest in U.S. Application No. 09/710,102, an application to which the '183 Patent claims priority, to Novacept, Inc.

B. U.S. Patent No. 9,095,348 ("the '348 Patent")

13. The '348 Patent is entitled "Moisture Transportation System for Contact Electrocoagulation."

14. The '348 Patent was issued by the USPTO on August 4, 2015.

15. The '348 Patent expires on November 19, 2018.

16. The '348 Patent claims priority to Provisional Application No. 60/084,791, filed May 8, 1998 (i.e., the '348 Priority Date). Original Utility Application No. 09/103,072, filed June 23, 1998, issued as U.S. Patent No. 6,813,520 ("the '520 Patent"). Application No. 10/959,771, filed October 6, 2004 was a divisional of Application No. 09/103,072, and issued as U.S. Patent No. 7,604,633 ("the '633 Patent"). Application No. 12/581,506, filed October 19, 2009, was a continuation of Application No. 10/959,771, and issued as U.S. Patent No. 8,506,563 ("the '563 Patent"). Application No. 13/962,178, filed August 8, 2013, was a continuation of Application No. 12/581,506, and issued as U.S. Patent No. 9,095,348 ("the '348 Patent"). The '520, '633, '563, and '348 Patents all share a common specification. Only the claims of each are different.

17. Cytyc listed Csaba Truckai, Russel Mahlon Sampson, Stephanie Squarcia, Alfonso Lawrence Ramirez, and Estela Hilario as named inventors on the face of the '348 Patent.

18. Hologic, Inc. is the owner by assignment of the '348 Patent.

19. Hologic, Inc. acquired the '348 Patent from Cytyc on January 15, 2016.

20. Csaba Truckai assigned his interest in the '348 Patent to Novacept, Inc. on August 5, 1998.

21. In August 1998, Csaba Truckai assigned his interest in U.S. Application No. 09/103,072, an application to which the '348 Patent claims priority, to Novacept, Inc.

22. Certain persons at Minerva had knowledge of the '348 Patent prior to the filing of the original Complaint.

III. THE NOVASURE SYSTEM

23. Menorrhagia, also known as Abnormal Uterine Bleeding or AUB, is menstrual bleeding that is abnormally heavy in amount and/or duration.

24. Endometrial ablation is a transcervical surgical technique in which the lining of the uterus is destroyed with the goal of preventing further bleeding.

25. Mr. Truckai and others at Novacept, Inc. developed the NovaSure system.

26. In 1993, Csaba Truckai co-founded Novacept, Inc.

27. Novacept, Inc. received FDA premarket approval for commercial distribution of the NovaSure system on September 28, 2001.

28. Novacept, Inc. assigned to Cytyc Corp. its patent rights including continuation applications.

29. Hologic markets and sells the NovaSure system throughout the United States and in interstate commerce.

IV. MINERVA AND THE MINERVA ENDOMETRIAL ABLATION SYSTEM ("MINERVA EAS")

30. Both the Minerva EAS and the NovaSure system are indicated for use on premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

31. The Array Opening Indicator of the Minerva EAS contains a Black Indicator Line that can move relative to rows of black dots depending on the degree of expansion of the Plasma Formation Array.

32. Csaba Truckai was involved in the development of the Minerva EAS.

33. Csaba Truckai is a founder of Minerva.

34. Minerva was founded in 2008.

35. Minerva received FDA premarket approval for commercial distribution of the Minerva EAS on July 27, 2015.

36. Minerva began commercial distribution of the Minerva EAS in August 2015.

37. Minerva markets and sells the Minerva EAS throughout the United States and in interstate commerce.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

1:15CV1031

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

ORDER

In conformity with the Memorandum Opinion issued this date,

IT IS ORDERED:

1. The parties' motions for oral argument (D.I. 354 and D.I. 359) are denied.

2. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion to strike argumentative exhibits (D.I. 346) is denied.

3. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion to bifurcate (D.I. 374) is denied.

4. The parties' motions to preclude or strike expert testimony (D.I. 279, 290, and 317) are denied.

5. Defendant Minerva Surgical, Inc.'s motion to dismiss (D.I. 275) is denied.

6. Defendant Minerva Surgical Inc.'s motion for partial summary judgment (D.I. 277) is denied.

7. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for a summary judgment of no invalidity (D.I. 287) is granted.

8. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for a summary judgment of infringement (D.I. 288) is granted.

9. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for summary judgment with respect to assignor estoppel (D.I. 289) is granted.

10. The action will proceed to trial for a determination of damages and willfulness in connection with the patent claim and for a determination of the parties' state-law claims and counterclaims.

DATED this 28th day of June, 2018.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

1:15CV1031

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

VERDICT

We, the jury, find by a preponderance of evidence, as follows:

I. PATENT DAMAGES

- As instructing in Instructions Nos. 13 to 22, we find Hologic is entitled damages for: (answer YES to only one)
  - ○ _X_ Lost profits (Answer question I.a)

    OR
  - ○ ___ Only a Reasonable Royalty (Answer question I.b)

I.a If you find that Hologic is entitled to lost profits answer the following:

- ○ For lost profits of $4,200,529.75 and,
- ○ For royalties for sales not included in lost profits $587,138.48, a royalty of 8 %

I.b If you find that Hologic is entitled to only a Reasonable Royalty:

- For a reasonable royalty $_____, a royalty of __%.

II. WILLFUL INFRINGEMENT

- As instructed in Instruction No. 23, we find Minerva's infringement of the '348 patent was

  ___ Willful

  _X_ Not willful

III. MINERVA'S COUNTERCLAIMS

A. Breach of Contract

- On Minerva's claim for breach of contract, as instructed in Instruction No. 35, we find in favor of

  ___ Minerva or _X_ Hologic

B. Lanham Act

- On Minerva's claim of false advertising under the Lanham Act, as instructed in Instruction No. 33, we find in favor of

  ___ Minerva or _X_ Hologic

If you found in favor of Hologic your deliberations are at an end.

If you found in favor of Minerva, answer the following:

- What is the amount of money required to compensate Minerva for any actual injury?

  $_____

- What is the amount of additional profits Hologic gained as a result of the false advertising?

  $_____

- Was Hologic's conduct willful?

  ____ Yes

  ____ No

Your deliberations are at an end. Please have your foreperson sign and date this form .

DATED this 27 day of July, 2018.

[redacted]
FOREPERSON

JURORS:

[redacted]

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No. 20-440

IN THE

Supreme Court of the United States

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

JOINT APPENDIX – VOLUME II

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PETITION FOR CERTIORARI FILED SEPT. 30, 2020
CERTIORARI GRANTED JAN. 8, 2021

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TABLE OF CONTENTS

NOTICE

The following documents have been omitted from the printing of this Joint Appendix. They may be found in the Appendix to the Petition for a Writ of Certiorari at the following pages:

[317] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Tuesday, July 17, 2018
9:00 o'clock, a.m.

VOLUME 2

BEFORE: HONORABLE JOSEPH J. BATAILLON,
U.S.D.C.J., and a jury

---

* * * *

[467] PLAINTIFFS' TESTIMONY

. . . EDWARD GORDON EVANTASH, having been duly sworn/affirmed as a witness, was examined and [468] testified as follows . . .

* * * *

DIRECT EXAMINATION

BY MR. WOLF:

* * * *

[511] Q. Now, you were here an hour ago when there were slides on the screen showing 2001 data for

NovaSure compared to 2017 data for the success of Minerva; is that right?

A. I was.

Q. In your opinion, in your experience, was that a fair comparison?

MR. BISH: Objection, Your Honor. Asking for opinion.

MR. WOLF: Your Honor, he submitted a statement and it's also corporate designee. I mean, I can --

THE COURT: Overruled. He can answer.

BY MR. WOLF:

Q. Go ahead.

A. I'm sorry. Can you reword the question?

Q. Was that a fair comparison?

A. Oh, no, no. I mean, the NovaSure has been around for 15 years and things have changed. Things have changed both in the device as I pointed out to you, in the generator, simplifying the way we do it, understanding the procedure [512] better and how physicians use the device, can insert it into the uterus, how they can deploy it and seat it.

Choosing the right patients. We've had so many articles, over 80 articles published on NovaSure, so we have an understanding of which patients might do better, which patients might not. It helps in our patient selection. All of these issues help contribute to success rates that we see are higher than we originally saw back in 2001.

Q. What's a peer-reviewed article?

A. So journals exist to published articles for physicians to read, and to find out new information, new data from studies that have been performed.

Some journals are call peer-reviewed journals. That means that they go through the process by which these articles submitted, the studies have been evaluated for both their significance, the credibility, their contributions, the way their methodologies are done, to determine if they are worthy enough of being published in these journals. And then they are, once edited, deemed acceptable for publication.

They come out in journals, many of which you've heard of, like New England Journal of Medicine, the Journal of the American Medical Association, or Lancet. In OB/GYN, we have what's called the Green Journal, the Gray Journal, Sterility. I will talk about these later. But a number of [513] journals that are peer-reviewed that provide the practicing OB/GYN with articles from studies that demonstrate what we call real-world data. How is this device being used by mainstream physicians? How is it being used by physicians doing clinical studies in the real world?

Q. Have there been peer-reviewed studies since 2001 that have been published that have talked about NovaSure's success rates?

A. Many.

Q. And have those peer-reviewed journals shown that NovaSure's success rates are comparable to Minerva, better than Minerva, or worse than Minerva?

A. Essentially comparable.

Q. Is there a reason why NovaSure's non-prejudice in the market from 2001 to 2014 might have helped Minerva get better numbers to its FDA study?

MR. BISH: Objection, Your Honor. It calls for speculation.

THE COURT: Yes. I would like to hear a little bit more foundation before he offers the opinion.

MR. WOLF: Understood.

THE COURT: Sustained.

* * * *

[531] Q. Let's just blow it back up altogether and look only at the bottom line, the grand total row. So we know from before that that fiscal years, up to 17,577. Let me ask you can you roughly add up how much you spent on R&D there?

A. Yes.

MR. BISH: Objection, Your Honor, on foundation. I'm not sure we have a basis for his knowledge for the number yet.

BY MR. WOLF:

Q. Are you familiar with the research and development programs at Hologic?

A. I'm familiar with the names, except for TOTO.

Q. And are you generally familiar with the budgetary process for research and development programs?

A. I am. Finance releases, yes.

Q. And you see it in your ordinary course of business?

A. I do.

Q. Okay. So then let me ask, roughly speaking, how much you have you spent on R&D from fiscal '08 to fiscal '17?

A. About 90 to 100 million.

Q. We can obviously add that up ourselves.

A. Okay.

Q. That's 90 to 100 hundred million. Does that include [532] money spent on physician training?

A. No.

Q. Does that include money spent on marketing?

A. No.

Q. Does that include money spent on education?

A. No.

Q. If we include physician training and marketing and education, how much more has been spent on NovaSure since the acquisition?

A. About 40 million.

Q. So if you include the 325 million you spent to purchase Novacept, 100-plus on R&D and the 40 million or so in total, how much have you spent to bring NovaSure to patients?

A. Roughly 450 million or so.

Q. Are you familiar with the term star product?

A. Yes.

Q. What does that mean in business lingo?

A. So that's a product that's in a market that's growing and the product is growing and you want to continue investing in it to make it even better, to continue to see its improvement so that you can continue to generate more revenue into the future.

Q. Is NovaSure a Star product?

A. It is.

* * * *

[537] BY MR. WOLF:

Q. And are you aware that during that window -- let me ask it differently. Has Minerva made public presentations about its technology at trade shows?

A. Yes.

Q. Can you look in your binder at PTX-270 -- oh . . .

(Pause while counsel conferred.)

MR. WOLF: May I approach, Your Honor?

THE COURT: Yes, you may.

THE WITNESS: Thank you.

BY MR. WOLF:

Q. Let's turn to the first page. Just look at it first.

Can you tell me what that document is?

THE COURT: Well, first, would you identify it

for the record as an exhibit number.

MR. WOLF: I'm sorry, Your Honor. PTX-0278.

Apologies.

THE WITNESS: Yes. So this is a program from the AAGL meeting. It stands for the American Association of Gynecologic Laparoscopy.

Q. And when is it dated?

A. It is November 6th through November 10th, 2011.

[538] MR. WOLF: Move the admission of PTX-0278.

THE COURT: Any objection?

MR. BISH: No objection, Your Honor.

THE COURT: 278 is received.

(PTX-0278 was admitted into evidence.)

BY MR. WOLF:

Q. If we can turn to the page ending 242313.

And let me ask you: I assume you've been to AAGL?

A. I go every year.

Q. The title of the page is technical exhibit description, and you see in the middle of the right-hand column Minerva Surgical?

A. I do.

MR. WOLF: Could you blow that up, please?

BY MR. WOLF:

Q. Could you please read allowed the description of Minerva's technical exhibit?

A. Minerva Surgical is clinically testing a new endometrial ablation system utilizing RF energy and argon plasma energy within a balloon. System attributes include: Total procedure time -- three minutes, small diameter device, large opened array, easy seating, cervical canal sealing balloon, easy removal, touchscreen plug-and-play controller. Visit their web page.

[539] Q. And how big is the conference that this is identified?

A. About 5,000 typically would attend.

Q. And physicians attend this?

A. They do.

Q. And competitors?

A. Yes, exactly. A lot of businesses attend.

Q. Does Hologic have its own booth?

A. Yes. Can I describe what booth it is?

Q. Yes?

A. There's this big conference where we have scientific exchange. People get up. They talk about abstracts or they give presentations that have been accepted. There's some educational and training programs and then there's this one area where all of the product, the medical device companies and some pharmaceutical companies have an opportunity to have booths where they show their product.

They showcase new products and it's an opportunity for them to engage and interact with physicians who can look at it and ask direct questions.

Q. Do you need to sign a nondisclosure agreement to attend this conference?

A. No, you don't need to have a nondisclosure agreement in place.

* * * *

[571] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Wednesday, July 18, 2018
8:34 o'clock, a.m.

VOLUME 3

BEFORE: HONORABLE JOSEPH J. BATAILLON,
U.S.D.C.J., and a jury

---

* * * *

[627] REDIRECT EXAMINATION

BY MR WOLF:

* * * *

DIRECT EXAMINATION

BY MR. WOLF:

* * * *

[632] Q. Is there any reason why Hologic might have been particularly uniquely concerned about Minerva as opposed to another competitor coming on the market?

MR. BISH: Same objection.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MR. WOLF:

Q. And what is that?

A. It was frustrating. We're competing against our own product with a balloon. It's a -- we're competing against many of our own previous reps. We are competing against inventors of our own device, and we were hearing claims from our physician customers that, yes, they told me it's the new NovaSure, that this is the -- you know, that this is, you know, what -- it looks like NovaSure, maybe a little better. That's what we were hearing. We were competing against ourselves essentially, and, yes, that -- that was -- that made us rather emotional.

* * * *

[879] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Thursday, July 19, 2018
8:32 o'clock, a.m.

VOLUME 4

BEFORE: HONORABLE JOSEPH J. BATAILLON,
U.S.D.C.J., and a jury

---

* * * *

[1042] . . . CHRISTOPHER C. BARRY, having been duly sworn/affirmed as a witness, was examined and [1043] testified as follows . . .

* * * *

[1151] RECROSS EXAMINATION

BY MR POPLAWSKI:

Q. Cytyc bought Novacept in about 2004?

A. Yes.

Q. And Novacept is the company that put the NovaSure product on the market in 2001?

A. Yes.

Q. And then Hologic bought Cytyc in about 2007?

A. Yes.

Q. And Hologic, since by Cytyc, including the NovaSure product, has made about $3 billion on sales of NovaSure product?

A. On the top line, correct. Sales, right.

Q. And so in essence here, and that's basically for all technology. Right? It has been on the market since 2001?

A. Yes. It has been around and it's established and still popular.

Q. So Hologic believes it should get well over half of Minerva's sales going forward as lost profits?

A. It's not going forward. The damages that we'retalking about are historical, the past sales.

Q. Okay.

* * * *

[1156] THE COURT: Mr. Truckai, if you would stand right there. We're going to ask you a couple questions and then swear you in.

. . . CSABA TRUCKAI having been duly sworn as a witness, and was examined and testified as follows . . .

MS. ELSON: Thank you, Your Honor.

And just to introduce -- let's get you set up here.

THE COURT: You may proceed, counsel.

MS. ELSON: We have binders.

Thank you, Your Honor. We are very pleased now to finally begin the presentation of Minerva's case.

I would like to introduce you to Minerva's first witness, who is Mr. Csaba Truckai, and he is an inventor and founder of Minerva, and I will now ask -- well, Mr. Csaba is on the stand.

[1157] DIRECT EXAMINATION

BY MS. ELSON:

Q. Good afternoon, Mr. Truckai. We'll at least give a little bit of an introduction and then we'll have to pick up again tomorrow.

Have you ever testified in court before?

A. No. It is the first time.

Q. Would you please introduce yourself to the ladies and gentlemen of the jury.

A. Good afternoon. My name is Csaba Truckai.

Q. And feel free -- there should be a mike.

THE COURT: If you just move it a little closer, it might help.

THE WITNESS: Okay. Thank you.

BY MS. ELSON:

Q. It's right there and there's water if you need it?

A. Thank you.

Q. All right. So where do you live, Mr. Truckai?

A. Saratoga, California.

Q. Do you have a family?

A. Yes, I do. Wife and three boys.

Q. Three boys?

A. Yes.

Q. Are you a U.S. citizen?

A. Yes, I am.

[1158] Q. Were you always a U.S. citizen?

A. No, I was not.

Q. And where were you actually born?

A. I was born in Hungary.

Q. Can you just briefly describe your studies in Hungary.

A. I had three years of pre-med and the fourth year I transferred to mechanical engineering.

Q. How long did you study mechanical engineering?

A. A year.

Q. I'm sorry?

A. A year.

Q. Okay. Now, when did you move to the United States?

A. 1984.

Q. Okay. Now, today, how would you describe your main line of work?

A. I'm inventing new medical devices, new technologies, and evaluating them, their application in the medical device field.

Q. How long have you been an inventor of new medical devices?

A. Close to 30 years.

Q. Okay. Now, where do you spend most of your time nowadays?

A. I'm still spending up to 14 hours in the lab, checking prototypes, devices, what's wrong with them, how we can fix [1159] it, how we can apply to various procedures.

Q. Okay. Now, have you prepared a list of the different types of medical devices that you have invented and developed over those nearly 30 years?

A. Yes. Yes, I did.

Q. Can we see that, please?

So can you just briefly for the ladies and gentlemen of the jury describe the different kinds of medical devices you've invented over those nearly 30 years.

A. I started in cardiac device market and I have a very unique patent for cardiac catheters. Angioscopy, the way you can look inside the heart and evaluate various plaques in the arteries.

Q. If you could speak a little more into the microphone and just a little slower?

A. I'm sorry.

Q. Okay.

A. Pulmonology for intubation. Cardiac ablation for arrhythmia.

Q. Arrhythmia?

A. Arrhythmia. Irregular heartbeat. Endometrial ablation, vessel sealing to replace sutures. Spinal fraction fixation. Spinal tumor ablation. Arthroscopy and orthopedic products. Fibroid resection and an enlarged prostate resection, BPH.

[1160] Q. BPH?

A. It's a prostate resection.

Q. Okay. Now, how many of these products that you have developed over those 30 years that are listed here are still being sold? How many of these products that fall in these categories?

A. The only one that's not sold is the angioscopy product and the orthopedic and the prostate product will be on the market in the next couple of months or so.

Q. Okay. So out of all of these, the only one that's not being sold is angioscopy?

A. That's correct.

Q. And this one is soon to be sold?

A. In a month or so.

Q. Okay. Now, are you a named inventor on any U.S. patents?

A. Yes, I am.

Q. Okay. How many issued? Let's start with issued U.S. patents?

A. I have over 160 issued U.S. patents.

Q. All right. And how about any pending United States patent applications?

A. Over 150.

Q. Okay.

A. Pending applications.

[1161] Q. All right. So roughly altogether, over 300 issued United States patents and pending applications? Inches approximately.

Q. Okay. Now, when the Patent Office issues you a patent, do you consider it your property?

A. Every issued patent is a property. Very important intellectual property that I own.

Q. Okay. Now, do you respect the intellectual property of others?

A. Absolutely.

Q. Okay. And why is that?

A. I respect it because I hope others are going to respect mine, too.

Q. Fair enough.

Now, after you arrived in 1984 in the U.S., what was your first job in the United States?

A. I couldn't speak English, so the first job I got was a graveyard shift in a hosptial. I was a nurse assistant.

Q. A graveyard shift in a hospital?

A. That's right.

Q. And your position was?

A. Nurse assistant.

Q. Nurse assistant. Okay.

A. And during the day, I went to English school.

Q. All right.

[1162] A. And I had to learn English.

Q. You did a good job.

What was your first job with an actual company here in the United States?

A. Cordis Corporation.

Q. Okay. And what was your last position? And what do we sear here?

A. This is just one of the devices from Cordis.

Q. Okay.

A. But it's a very broad range of products. It's a very large company.

Q. And what was your last position -- when you left Cordis, what was your title or position?

A. I was a senior R&D engineer in custom products.

Q. Okay. Now, what kinds of products did you personally develop while at Cordis? And if it helps you, we have it here on the screen?

A. This is one of the products which I'm pretty proud of. We call it a Brite Tip Guiding Catheter. The catheter introduces the device into the coronary artery. Pressure. That's for evaluating heart valve function.

Q. Evaluating heart valve function?

A. That's right. But generally speaking, the braiding technology which I developed used today about 6 to 10 million catheters. So most of the products that Cordis has [1163] has my technology.

Q. Okay. You said braiding technology?

A. Braiding.

Q. Do we see that here?

A. That's right. The mesh you see on the device here, the wire structure is call the braided wire structure.

Q. Okay. So is the -- you said this product is still on the market?

A. That's right.

Q. All right. So what was your next job after leaving Cordis?

A. I joined a company in California called Advanced Cardiovascular Systems.

Q. Advanced Cardiovascular Systems?

A. That's correct.

Q. Okay. Was that also in Florida?

A. Unfortunately, not. I had to move to California.

Q. Okay. And is that where advanced cardiovascular was located?

A. Yes. In Santa Clara, California at the time.

Q. And what was your position at Advanced Cardiovascular Systems?

A. I was a senior R&D engineer and project lead engineer.

Q. All right. By the way, did you apply to them for a [1164] job?

A. Actually, no. End of 1989, they called me, that they would like me to join them and run this project for the company.

Q. Okay. So they sought you out?

A. They did.

Q. Okay. Now, as a lead engineer, what products did you develop while at Advanced Cardiovascular Systems?

A. It was two products, the an gee yo scope and guide wire.

Q. What?

A. It's called a guidewire.

Q. Guidewire?

A. Fine filament, which goes in the center lumen of this catheter.

Q. And is Advanced Cardiovascular Systems still around?

A. Yes, but they why bought by a large company called Abbott.

Q. They were purchased by Abbott?

A. That's right.

Q. Okay. Abbott Laboratories?

A. Yes.

Q. Is that a large company?

A. It's a very large company.

Q. And where did you go next?

[1165] A. After that, I joined a very small startup company called CardioRhythym.

Q. Can you spell that, please?

A. My spelling is not the the greatest.

Q. Okay. Oh, let me give it a try.

C-a-r-d-i-o-R-h-y-t-h-m.

A. That sounds right.

Q. Where was CardioRhythm located?

A. In California.

Q. And what did you do -- what did you develop at CardioRhythm?

A. Developing radiofrequency-based cardio devices. And actually, we request see it here on the picture.

Q. Yes.

A. One of the slides.

Q. And is CardioRhythm still around?

A. No. Medtronic bought at the very early stage.

Q. Okay. Medtronic?

A. Medtronic, which is again a very large, probably the second largest medical device company in the world.

Q. Are the products you developed while at CardioRhythm still on the market?

A. Yes. I'm not sure what you can see here is identical. The only thing they changed is the color.

Q. Of this?

[1166] A. That's right.

Q. Now, when you started at CardioRhythm, did you work there exclusively?

A. No. When I joined the company, I talked to the CEO and the founders and I told them that I would like to run my own company some day, and would they mind if I start on not interfering with the company business, starting my own company, and they agreed.

Q. So this is before you even started, you worked something out up front?

A. Absolutely right.

Q. All right?

A. I felt like it's the right thing to do because if they don't like it, I don't want to interfere with them. But I told them that it would not interfere with the business and I would do everything I need to do to make sure that the company is successful and acted actually it turned out very well because it was such a startup company, they had nothing, and I had more equipment in my garage, you know, from equipment and other

devices, that, you know, actually used to build their first devices.

Q. Now, so far, are any of these products you talked about so far, are any of these companies you talked about so far Minerva?

A. I'm sorry?

[1167] Q. Are any of these companies or products that you've talked about so far, are any of them Minerva or Minerva products?

A. No.

Q. Okay.

A. Absolutely not.

Q. So how did you manage to do both your own company on the side and work for CardioRhythm?

A. I work a lot, so I start usually around, at the time, around seven, and I was there until 11:00 or 11:00 o'clock at night.

Q. There, where?

A. At the company.

Q. All right.

A. And I went home and I started to do my own business like 3:00, 4:00 in the morning, and it started again the next day.

Q. And was that your lab in your garage?

A. That's correct.

Q. Now, what happened eventually to your own side startup?

A. So we called the company KST Medical and eventually over many name changes, it ended up Novacept.

Q. Okay. And when did you formally, can we see the slide -- are we seeing here the prior company up here?

[1168] A. That's correct.

Q. All right. And so when did you formally kick off Novacept?

A. 1993.

Q. Okay. And what inspired you to found Novacept?

A. Well, we were working on endoscope, and one of the products was a hysteroscope.

Q. Excuse me. A what?

A. Hysteroscope.

Q. Hysteroscope?

A. That's correct. That's a device, you can look inside uterus and I was talking to gynecologists in the bay area.

Q. Gynecologists?

A. Gynecologists. They talk about the problems they have and one of the problems, they mentioned that it's a big issue for them, was endometrial ablation. It was very technique dependent and the new devices, they didn't always address the issues --

Q. And I am sorry. The new devices didn't?

A. They didn't address some of the issues they considered to be important.

Q. All right.

A. On a personal note, you know, my mother had, you know, this problem, and in her mid-forties, you know, she went through a hysterectomy. So even then I thought, there has [1169] to be a better way to deal with this problem.

Q. Okay. And what was wrong? What did you find was wrong or deficient about the existing technology?

A. Partly.

A. The part I was interested in the radiofrequency devices, try to address this issue, and I found that the liquid buildup they have on the surface, preventing these devices to work normally, or function the way they should.

Q. Did you say the liquid buildup?

A. Liquid buildup on the surface of the device and the tissue.

Q. Okay. And so were there electrodes on the surface of the device?

A. So, yes. If you have a -- if you have radiofrequency electrodes on the surface, you have to make direct contact with the tissue, and when you apply energy to the tissue, radiofrequency energy, you know, the fluid from the tissue can come out.

So only way I can explain, if you grill a steak, you put it on the grill.

Q. First, would you explain, what causes biologically -- what causes the moisture to build up?

A. So if you heat up the tissue, all the collagen structure constructs in the tissue and the moisture oozes out from the tissue.

[1170] So just like I mentioned that, you know, if you put a steak on the grill, you can see the same process. You know, the liquid comes out, and that liquid is actually very conductive. It's filled with salt, very conductive, and current is bypassing the tissue, but rather goes through this liquid layer. Two things.

Q. Let's break this up a little bit. The liquid that you come out you said is saline?

A. It's almost like, it's very conductive.

Q. Okay.

A. It's high salt content.

Q. Okay.

A. So it's conductive.

Q. It conducts electricity?

A. That's right.

Q. Okay. And what is it that happens to the electricity? I apologize for interrupting. Go ahead.

A. So two things happen. The first thing is liquid buildup pushes it away from the tissue. You're losing the direct contact.

Secondly, between this liquid layer is channelled energy. It's almost like shorting. So you are no longer running the current through the tissue, but rather this liquid layer and that prevents the device to function normally.

[1171] Q. Is it fair to say current was getting diverted into this liquid layer?

A. Not just diverted. The current that's required is extremely high, which I considered unsafe.

Q. Okay.

Q. In your experience, what is wrong with using more current than necessary in the human body?

A. So, you know, you've got to look at the safety aspect, and I always thought, you know, if you can do something, a minimal amount of energy, do it with minimal amount of energy.

The reason why if something goes wrong, we are putting a large amount of current in the tissue, the side effect can be devastating. You always want to minimize the amount of current you put into the tissue.

MS. ELSON: Your Honor, we've actually reached a transition point. This might be a good time to take a break, break for the day.

THE COURT: That's fine.

So, ladies and gentlemen, I asked Ms. Elson to introduce you to this witness and she has done that. We will continue his testimony tomorrow morning at 9:00 o'clock.

I will again remind you, don't talk to anybody. Don't do any research. This is your decision, nobody [1172] else's. So keep an open mind until you've heard all the evidence and I will see you tomorrow morning at 9:00 o'clock.

(The jury was excused for the evening recess.)

THE COURT: The record should reflect we're outside the presence of the jury and everyone may be seated.

Mr. Truckai, you're welcome to step out of the courtroom if you would like to.

THE WITNESS: Okay. Thank you.

(Witness excused.)

* * * *

[1178] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Friday, July 20, 2018
8:32 o'clock, a.m.

VOLUME 5

BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[1201] Welcome back. We are going to continue the examination of Mr. Truckai.

Ms. Elson, you may continue.

MS. ELSON: Thank you, Your Honor.

. . . CSABA TRUCKAI, having been duly sworn as a witness, and was examined and testified further as follows . . .

DIRECT EXAMINATION, Continued.

BY MS. ELSON:

Q. Good morning. So, Mr. Truckai, we're going to just recap a little bit to see where we left off. We were talking about the early days at Novacept.

Do you recall?

A. Yes.

Q. Okay. And we were talking about the problem with the existing technologies when we were first thinking of developing the NovaSure.

Do you recall?

A. That is fine.

Q. Okay. So can you just recap for us, what was the problem with those older devices in general?

A. All of them, you know --

Q. Can you lean just a little closer to the mike?

A. Is that better?

Q. Yes. Thank you.

[1202] A. Okay. So all of the devices were having the same issue that a liquid buildup on surface of the electrode, between the electrode and the tissue caused the ablation process, not to path 1. But they should -- but that liquid layer, the gap and also electrically conductive liquid channelled energy not into the tissue, but through the liquid layer, between the coat, and that was one of the fundamental issues, also causing current needed to run the process.

Q. All right. So a gap between the tissue and the electrode?

A. Developed, and the liquid started a buildup, and the liquid came from the tissue, which I explained, the process, squeezed the moisture out from the tissue.

Q. And why couldn't the older device, why couldn't the liquid come out?

A. Because they had like a solid surface, either ceramic backing, or they had a balloon like, you know, one of the devices.

Q. All right.

A. So the moisture has no way to escape from the location. It just keeps collecting.

Q. Okay. And so yesterday's we were discussing that was the problem. So can you tell us, what was your solution to that problem of liquid buildup in the uterus?

[1203] A. Our solution was moisture transport system and the moisture transport system does exactly as the name defines it. The moisture, which, you know, squeezes out from the tissue, you know, the suction, removed it from the ablation site, and that's a pristine, clear, dry condition for that conducting the tissue. So the liquid would not build up, the electrode is always making contact with the electrodes, and the current always was passing through the tissue.

Q. Okay. And when, roughly, when did you come up with your solution of moisture transport?

A. 1996, when we started ablation.

Q. Okay. So what do you now see here?

A. This is the NovaSure electrode head. You can see the gold color, the electrode. You know, this white color is the inner layer, so this is two opposing for any given

moment, point in time. And here on the magnification, we can see how porous this electrode is.

Q. How porous?

A. Yes. It's a metallized fabric. Actually, what we used was this Lycra that we sent out to be metallized, and that's the way we formed the electrode in the early days.

Q. All right. If we could go to the next slide, please.

So what do we see here on the left? Start with [1204] the left.

A. So, you know, if you would strip away this electrode mesh, this porous electrode mesh, you would see, you know, the interior. And the most important part of that is the suction. And the reason why that was a very important portion, because all the moisture, the gap, the seems generated during the ablation process was suctioned out here and outside, to the outside of the uterine cover.

Q. Thank you.

MS. ELSON: Your Honor, I'm thinking, would it be all right if we put something beneath Mr. Truckai's mike to lift it up a bit?

THE COURT: I think you can -- yes. Do whatever you want to do. It doesn't matter to me.

MS. ELSON: I'm going to scrounge up a binder somewhere. There you go.

THE COURT: We'll see how it goes along. The microphone might be overloading a little bit, too, and cutting out. If it doesn't work out very well, we'll take a break.

MS. ELSON: I think he's taller than the mike was.

THE COURT: All right.

MS. ELSON: Okay. Thank you.

BY MS. ELSON: [1205] Q. Now, have you prepared an animation, Mr. Truckai, to illustrate the problem and your solution?

A. Yes, I did.

Q. Okay. So what do we see here?

A. So this is the old technology. What you what you can see here is a balloon.

Q. This is the old technology?

A. This is the old technology which existed prior to I started experimentation with our device.

Q. You'll have to talk a little closer to the mike.

A. Okay. So this device, you can see is based on a bubble surface. So it's a known permeable, nonporous. So those electrodes are glued on or molded on the surface.

Q. Okay.

A. And it's positioned inside the uterine cavity. You can see this triangle shape, generally speaking, and the device is approximating the size and the shape of the uterine.

Q. This was one of the older-type devices?

A. This is one of the older-type devices.

Q. Next, please. So what do we see here?

A. So if you would magnify only this area here, you know, that's what you see. You can see the tissue, which is the endometrium, and you can see this is the balloon and this is the balloon interior. And you can inflate this balloon with [1206] either air or fluid.

The point I'm trying to make here, this electrode is coming in close contact with the tissue. The balloon is forcing the electrode to be pushed against the tissue.

Q. So you can place the balloon and push the electrodes against the tissue?

A. That's right.

Q. Okay.

A. And you can see hear the positive and the negative. It's just showing the two, and current starts to flow through the tissue, heats up. The liquid is driven out from the tissue and builds up. It's pushing the electrodes apart and the current goes from one electrode to the other versus going into the tissue and going back to the other electrode. That's a fundamental issue of the technology.

Q. All right. And was that basically shorting the electrodes?

A. Technically, a different type of short. I would say 90 percent of the current channelled through the liquid versus channelled through the tissue.

Q. Okay. Instead of going to the tissue, where it's supposed to go?

A. That's right. The goal is to get energy into the tissue, not the liquid layer.

[1207] Q. Next, what do we see here? Next, please. What is this?

A. So this is, as you can see, the same triangle shape. This is a NovaSure device with, again, the two opposing at any given point in time, and it opens up and it's approximating the uterine cavity size and shape.

Q. Okay. Next?

A. This is --

Q. So how does your NovaSure solve the problem of moisture buildup?

A. So, again, if I magnify this little area, you can now see how this metallized fabric, you know, was constructed. And you can see there are huge openings on it.

So the current passes from this electrode structure into the tissue, but then moisture is generated. That moisture was actually drawn through that porous mesh.

Q. Can you see the next slide? The next step? What's happening here?

A. So this is just showing that, you know, that the electrode heats up, that moisture is drawn through this mesh, like a filter, and that suction that I mentioned before, all of this moisture was channelled through this, the porous mesh.

Q. Can we go to the next set. So what's happening here?

A. This is the suction that I just talked about, and that [1208] moisture is being drawn everywhere, every direction. It's pulling the seems, the moisture, keep it dry at all times.

Q. Okay. And do you have a name for your solution, or did you back then?

A. We called it just like, you know, named here, moisture transport system.

Q. You can take that down.

Did there come a time when you filed an original application relating to your moisture transport system?

A. 1998, May 8th.

Q. And if you could turn, please, in your binder, that one, to DTX-16.

A. Yes.

Q. Okay. And what is, what do you see there, Mr. Truckai?

A. I see my original patent, moisture transport system.

Q. Are you a named inventor on that patent?

A. Yes. I'm the named inventor.

MS. ELSON: Move to admit, Your Honor.

THE COURT: Any objection?

MR. WOLF: No objection, Your Honor.

THE COURT: It is received.

(DTX-16 was admitted into evidence.)

MS. ELSON: We can show it on the screen, [1209] please. Just zoom in at the top.

BY MS. ELSON:

Q. Again, now that we can all see it, Mr. Truckai, what is this?

A. This is the original patent that was filed. You can see here, which is the '520 patent, which we're talking about. It says the title. It shows the title that is the moisture transport system, as you can see here, for coagulation. You can see the inventor, the person, me here, and the others, you can see it has been

assigned to Novacept, and you can see that, you know, it's filed -- actually, you can see the patent application. It's for that one. It's 1998, June when it was filed.

Q. Can you go to the abstract, please. What do we see here? What is this telling you?

A. Very short, describes what the invention is, and the invention was permeable to moisture.

Q. Permeable?

A. That's right. Permeable to moisture although to mount an electrode carrying member on it. And through this permeated electrode member, the moisture can leave the ablation site.

Q. Is there a simpler way of putting electrode carrying member?

A. It was a host metallic fabric.

[1210] Q. The fabric we saw earlier?

A. That's right.

Q. If we could go to DTX Figure 23, please. DTX-16, Figure 23.

What do we see here?

A. This is the -- in the patent, this is a drawing representation of our proposed property.

Q. The porous fabric?

A. That's right. Electrode mesh.

Q. Okay. If we could go to Figure 26(a). What do we see here at the top, this upper half?

MR. WOLF: Your Honor, briefly, just for presentation purposes about claim construction issues, we would object to this line of questioning.

THE COURT: All right. I'm overruling it, but you're asking a continuing objection?

MR. WOLF: Yes, Your Honor.

THE COURT: All right. I will give you a continuing objection, but I have to know when the continuing objection stops, so when it stops, would you please stand and let me know?

MR. WOLF: I will do my best, Your Honor. Thank you.

THE COURT: Thank you.

Ms. Elson, you may continue.

[1211] MR. WOLF: Thank you, Your Honor. If we could go to the upper half and zoom in.

BY MR. WOLF:

Q. What do we see here, Mr. Truckai?

A. This is a magnified representation of our porous metallized mesh.

Q. The porous metallized mesh?

A. That's right.

Q. All right. And this is in the patent?

A. This is in the patent.

Q. And Figure 28, please. And if we could zoom in on the center figure. Thank you.

And what is this illustrating, Mr. Truckai, in your '520 patent?

A. The very thing I was talking about, that all the moisture, which was transmitted through that mesh was suctioned out through the suction, too.

Q. And did any of the examples, sometimes called embodiments described in your '520 moisture transport patent, describe a head with a, an exterior that liquid could not flow through?

A. None of them, because it would defeat the purpose. It would not work, just like the prior device.

Q. I'm talking about examples of your invention.

A. That's right. None of them.

[1212] Q. Now, do any of your early patent applications in this moisture transport family say anything about using plasma?

A. No.

Q. Now, given what we've seen in your '520 patent, what was your belief about the nature of the property that Novacept sold to Cytyc?

A. Well, the most important part of this moisture transport system, which we've been talking about.

Q. Okay. Can you say that just one more time slowly?

A. So the most is that the very subject, the moisture transport system for electrocoagulation is metallic mesh that all the steam moisture go through and suction out from the ablation cite.

Q. So that was your understanding what was sold to Cytyc?

A. That was my understanding.

Q. Did you ever think that when that what Novacept sold to Cytyc covered in a handpiece a head that used plasma to ablate tissue?

A. No.

Q. Now, could you turn to, let's go to column 19, and in particular, claim 1 of that same '520 moisture transport patent. What do we see here?

A. It describes the same thing we've been talking about. This is a fluid permeable elastic member. This is the same [1213] porous metallic fabric which we've been talking about.

Q. Okay. This is in the claims of the '520?

A. That's right. This is claim number 1.

Q. Do all of the claims in the '520 patent require 'fluid permeable elastic member.'

A. They are.

Q. Now, when you -- let's go back a little early to when you filed the application for this '520 patent.

Was there one claim, and if we could pull it up and see what I'm talking about. Let's zoom in on claim 31.

Was there one particular claim that you submitted along with your application that did not require a fluid permeable exterior?

A. Yes. When we filed the patent, the broader application, broader description of the patent, but the patent examination, one of the --

THE COURT: All right. Let's stop. We're losing the microphone.

This is a technical issue that requires somebody way over my training, so let's take five minutes, ladies and gentlemen, and ask IT to come in and restore the original configuration.

All right. So let's take five minutes.

(The jury was excused for a short recess.)

[1214] THE COURT: I think when we changed out the microphone, this microphone is not set up, generally speaking, to hook into the system for this particular input, and so they put something to kind of translate the two, and then they turned up the gain on this microphone, and I think it's shorting, it's cutting out. So we're going to have to go back to the original system, which the system is designed for, and then we'll just have to put it close to the witness and hope that it works.

MS. ELSON: Because what I'm hearing is that it's perhaps because he's breathing into the mike?

THE COURT: I don't know.

MS. ELSON: Okay.

THE COURT: But we'll have the IT guy come and then we'll figure it out.

MS. ELSON: Thank you, Your Honor.

THE COURT: So we're on a short break.

MS. ELSON: We appreciate the accommodation.

(Short recess taken.)

- - -

(Proceedings resumed after the short recess.)

THE COURT: Please be seated.

Let's get the jury.

(The jury entered the courtroom.)

MR. WOLF: Your Honor, may I suggest I get the [1215] last question and answer?

MS. ELSON: I will recap.

MR. WOLF: Thank you.

(The jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

I believe we have the problem solved, so you may continue, Ms. Elson.

MS. ELSON: Thank you, Your Honor. We resolved the technical issue.

BY MS. ELSON:

Q. So, Mr. Truckai, you were looking at JTX-15, and in particular, the application that you filed that ultimately led to your '520 patent.

Do you recall that?

A. Yes, I do.

Q. Okay. And just to recap, first I just want to know, was this the one claim in that application that didn't require a fluid permeable exterior?

A. That's right.

Q. Okay. Did claim 31 ever issue as an actual issued claim?

A. No. It was canceled.

Q. And why did you cancel it? Yes, perfect. Yes, go ahead.

[1216] A. Because during, submitted it after the examiner brought it to our attention that it's prior art. We reviewed it and we agreed that this is too broad, and our invention is actually the proposed metallized fabric moisture transport system.

Q. Now, let's go back to the timeline to after you completed how you filed your application for the NovaSure product, what was your next project?

A. My next project was SurgeRx. It's a company, radiofrequency tissue, which means we, using a very simple instrument, sealing vessels and veins.

Q. Like blood vessels?

A. Like blood vessels. You didn't have to use staples or sutures.

Q. No need for a staple or suture?

A. It speeds up the procedure. You didn't leave anything behind.

Q. This is for sealing blood vessels?

A. That's correct.

Q. What do we see next? What is this?

A. This is probably the most recent product for the EnSeal product.

Q. This is the product you were just talking about you developed?

A. That's right.

[1217] Q. Okay. Can you just describe it briefly?

A. You can see these are instruments. This is what a physician holds. At the end it's a structure that has clamps, hold the vessels between, compress it together, apply energies, melts vertically the wall in the vessel, fuse it together and in the middle, we could dissect it.

Q. Very good. If we could have the next slide, please.

And what do we see here?

A. That's a trade show. We went to it every year. AAGL.

Q. American Association of Gynecological Laparoscopists?

A. That's right.

Q. Thank you.

A. So this is the largest surgical show for Gynecologists since our device was used for hysterectomy to cut through the ligaments, both sides of the uterus. You know, we had a booth there. You can see SURGRx.

Q. This is your company, SURGRx?

A. That's right.

Q. Can we zoom in on the left there? Is that the product we were just looking at?

A. That's right.

Q. So is SURGRx still around as a company?

A. No. In 2008, Johnson & Johnson, they brought it.

Q. They bought it?

A. Yes.

[1218] Q. Is your EnSeal product still being sold by J&J today?

A. Yes.

Q. Okay. If we could go to PTX-278, please.

THE COURT: So, Mr. Wolf, I assume your continuing objection has ended?

MR. WOLF: Yes, Your Honor. I apologize. Yes. Thank you.

THE COURT: Thank you. You may continue, counsel.

MS. ELSON: Thank you. Thank you, Your Honor. If we could have that up again.

BY MS. ELSON:

Q. Okay. So what do we see here, Mr. Truckai?

A. This is an AAGL journal they publish before the AAGL meeting. So this is the cover page of it. Fortieth year of AAGL.

Q. Do you attend the AAGL?

A. Every year.

Q. Every year. If we could go to PTX-278 at 2306. What are we looking at here?

A. This is a trade show floor where you can see the various companies that demonstrate their products for the surgeon.

Q. Is this part of the same brochure?

A. Yes.

[1219] Q. All right. And what is shown here highlighted in yellow?

A. You know, these are the companies who are selling, or the companies my product being sold one way or the other.

Q. Okay. So these are all companies who are selling a product that you developed?

A. That's right.

Q. All right. Let's go on briefly. What was your next project after SURGRx?

A. The next project was DFINE.

Q. Okay. And just briefly, if you could tell us, what did the DFINE product do?

A. DFINE product was for vertical compression and also for vertebral tumor.

Q. Vertebral tumors?

A. That's right.

Q. Okay.

A. So the issue was that of a woman's age or man's age, the bone density loses. You can have a fracture. It's extremely painful.

Q. It's extremely painful?

A. Painful. That's right. And the technique they used in the past was a bone cement. Bone cement.

Q. So the old thing was the bone cement?

A. And it took about 30 minutes and it resolved the pain, [1220] so it was very effective. However, it did not resolve the compression. The patient stayed in a hunchback.

Q. The patient would stay hunchback?

A. That's right. We came up with a brand-new technique where we were able to increase the viscosity of the bone cement, that we elevated the height of the vertebral body. It's not just the pain, but the patient has a straight posture.

Q. So the old solution to carry the pain, that the patient was still hunchbacked?

A. That's correct.

Q. With your solution, you took care of the pain and the patient was able to straighten up?

A. Yes.

Q. And is DFINE somewhere else?

A. Yes.

Q. Okay. Were they acquired at some point?

A. Yes.

Q. Now, what was your next company?

A. Minerva.

Q. Okay. Now, when did you found Minerva?

A. 2008.

Q. Is Minerva a Delaware corporation?

A. It is.

Q. Okay. Now, so by the time you started Minerva, how [1221] many years had it been since you designed the older NovaSure product?

A. About ten years.

Q. Ten years?

A. Yes.

Q. And are you president -- at the time when you founded it, were you president and CEO of Minerva?

A. Yes, I was.

Q. Okay. Did there come a time when someone else assumed that position?

A. Yes. In 2011, Dave Clapper took over for me.

Q. Okay. And did you remain on the Board of Directors?

A. Yes, I am.

Q. Okay. At a high level, what's your role as the director?

A. I go to the board meetings. Management of the company, make the presentation at the company. R&D, sales, various corporate subjects.

Q. Okay. Including sales?

A. That's right.

Q. Now, were you a member of the board when Minerva began to actually sell its product?

A. Yes, I was.

Q. Okay. And so did the board have to approve the launch and sale of Minerva's product?

[1222] A. I'm not sure the board had to approve it.

Q. Well, collectively, did the board approve the launch and sale of Minerva's product?

A. Absolutely.

Q. Okay. And let's see. We'll move on.

So are you aware that Hologic has alleged that Minerva copied the old NovaSure product, the handpiece?

A. Yes, I am.

Q. Okay. And let's see. I guess we've seen it now several times. If you held up the two devices, the handpieces side by side from a distance, they appear to have a similar shape. So why do you believe that, nevertheless, Minerva did not copy the NovaSure product?

A. It can be very deceiving. You know, there are devices on the market prior to NovaSure that has very similar shape. You know, handle, controller, handpiece.

Q. Okay. Now, do you personally have knowledge of an older device that predated even the NovaSure with this same general shape?

A. Yes, I am.

Q. Okay. And what device was that?

A. That was the Vesta device.

Q. Now, when did you become aware of the Vesta device before you completed your design of the NovaSure?

A. In 1995, when I reviewed their patent.

[1223] Q. Was that before you completed your design of the NovaSure?

A. Way before.

Q. Way before?

A. Way before.

Q. Okay. Can we see the next slide, please?

And what are we looking at here?

A. This is the Vesta disposable device. You can see a slender shaft, a handle. What you don't see here, the connection that goes to an outside controller. On the shaft, you can see the tip.

This is enclosed within this, so the sheath was pulled back, exposing the triangular shape. You can see the electrodes on the surface of the balloon.

Q. So am I correct that this portion here is inside here?

A. That's correct.

Q. Okay.

A. It's easier at this point, the physician, when they put it into the uterus, they pull back the sheath and exposing this triangle shape, applicator.

Q. Is this the portion that would go inside the uterus?

A. That's right. I call it the business end. This is the most important part of the entire product. The rest of this is -- it's really just a shaft and a handle. Every [1224] device has a shaft and a handle.

Q. And was the Vesta system that you even be countered in '95, I think you said, was that an endometrial ablation device?

A. Very specifically designed for endometrial ablation. They called it at the time global endometrial ablation.

Q. Let's go to the next line. What do you see here?

A. The same thing. You can see the business end is enclosed within the shaft, the handle, and you can see the controller that they used, and that's it. So that is the entire system here.

Q. Okay. And if we could go to JTX-18, the cover, and zoom in on the upper half, please.

Okay. What do we see here?

A. So --

Q. If we could start with what's up in the upper right?

A. So just like with every patent, you can see this is the patent number. The last three digits, the '470 patent. You can see, you know, it was Vesta Medical who it was assigned to. That was the company, intellectual property. You can see it was filed in 1993.

You also can see it was issued in 1995, August 22nd, about a year earlier before we started the NovaSure project.

Q. And if we could also highlight the title. What does this tell us?

[1225] A. The title, it just says this is a device for endometrial ablation.

Q. Okay. Now, if we could go to Figure 12 of that same '470 patent, so that's the patent?

A. Yes.

Q. And what do we see here?

A. This is a drawing representation we just talked about.

Q. All right.

A. You know, the triangle shape, applicator head, the slender introducer, some sort of handle, and then the controller.

MS. ELSON: If I may, Your Honor, step over here.

THE COURT: Which exhibit are you handling?

MS. ELSON: Thank you, Your Honor. It doesn't have a label, but this is the -- oh, here we go. JTX-47.

THE COURT: Thank you.

MS. ELSON: It's the NovaSure Advance, I believe.

THE COURT: All right.

BY MS. ELSON:

Q. So, Mr. Truckai, did the -- what's shown there have the same general shape as the NovaSure?

A. It has to. You know, I cannot put a square device into a triangle shape.

[1226] Q. Okay. And your patent was filed in 1993?

A. That's correct.

Q. Okay. Can we go to the next slide, please.

So what do we see here? Let's start with the right.

A. Okay. So, again, just as I described, 190 is a triangle shape, applicator head. You can see a slender tube, which actually is slidable, so you can hide head to put in. You can see a handle. It's nothing specific, but the handle was described in the patent to objection date the sheath, you know, to move over enough from the energy applicator head, and a controller that controls the radiofrequency ablation process.

Q. Now, at the time you filed your '520 application for your moisture transport invention, did you disclose this earlier Vesta patent to the Patent Office?

MR. WOLF: Your Honor, we're back to the continuing objection.

THE COURT: Overruled, and you may continue.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. So did you disclose this older Vesta patent to the Patent Office?

A. Yes, I did.

Q. And why was that?

[1227] A. For the very same reason you asked me at the very beginning yesterday. Do I value other intellectual property of others?

Q. Do you value?

A. I am. And I feel it's very important for me to provide the Patent Examiner all the intellectual

property which relates to the product I'm submitting for invention, to evaluate that subject, and in this case, it happened. You know, this is a very important disclosure to the Patent Office.

Q. All right. Could we go, please, to the background section of DTX-16, the '520 patent, the written part of the patent, of the background section, please.

All right. And with a do we see here, Mr. Truckai?

A. So the patent we filed, the '520 patent, we clearly described that there is a device out there, you know, prior to our invention.

Q. Prior art?

A. Moisture transport. Prior art. It describes that it has an expandable bladder with electrodes on its outer surface.

Q. Just so we're clear, that's the '470 patent you're disclosing to the Patent Office in your application?

A. That's right. That's right. That was one of the [1228] patents among many that we disclosed.

Q. Now, did you consider this general shape of the NovaSure handpiece to be your invention?

A. Not at all.

Q. Okay. And what did you consider your moisture transport invention to be?

A. Exactly what you just said. This is the business end, moisture transport that posed electrode mesh that holds the seem to go through and away from the ablation site.

Q. Now, I'd like to just now jump ten years into the future and talk about Minerva's device.

What did you consider to be the most critical component of Minerva's device?

A. Very much the same thing. You know, the very end, the end of the applicator, because that's what's doing the procedure.

Q. And what does Minerva call that business end of its device?

A. We named it PFA, plasma formation array.

Q. Plasma formation array?

A. That's right, because it really describes the energy source we're using the plasma energy to ablate the tissue.

Q. All right. Can you just tell us just briefly, what is plasma? Briefly, if you can?

A. It's ionized gas, so it doesn't tell us too much. But [1229] the best way I can describe it, if you look up in the sun, it's all plasma.

Q. Okay.

A. So plasma is the most common material, you know, in the universe.

Q. So could we put up slide DDX-7-36, please.

Okay. So what do we see on the left?

A. On the left, the device we've been talking about, the porous electrode mesh with a metallized fabric.

Q. And on the right, ten years later, what do we see?

A. So this is, you know, the Minerva energy applicator head. This is plasma energy. What you see here, you know, internally, circulated. Those little filaments, okay, they are scanning the silicone

material membrane surface and they're looking for on the other side tissue which hasn't been thermally treated yet.

Q. Ablated?

A. Ablated.

Q. Now, did you ever believe, or were you aware of anyone at Minerva believing that Minerva covered the NovaSure?

A. No, I didn't. I don't know how. So different.

Q. Okay. Now, what did you -- let's see. Is there anything else like Minerva's plasma formation array on the market as far as you know?

[1230] A. I'm not aware of anything remotely.

Q. As far as you know, do any of the NovaSure variations along the way use plasma in any way to ablate tissue?

A. No.

Q. All right. Have you prepared a summary of the, what you consider the advantages of the Minerva over the NovaSure?

A. Yes, I have.

MS. ELSON: Can we bring that up, please?

BY MS. ELSON:

Q. Okay. Just briefly, we've heard some of this, but can you just briefly touch on what some of the advantages are as far as you believe?

A. So, first of all, you have a very smooth slippery silicone membrane, non-stick. NovaSure has a rough metallized fabric. We are controlling the ablation steps. We call them plasma streamers. You can see the

little filaments kind of moving around. Those are the ones seeking out where there is un-ablated tissue. So this is a completely different mechanism. You know, the plasma streamers. We have a smaller diameter. That means, you know, that it's easier to insert.

We used a small portion of the power. You know, you say here one-fourth of the power. Very likely, that's one fourth of the power, which is great, because you want to [1231] put the minimal amount of current into the patient. Because of the silicone, you are able to retain the moisture.

My pointer died.

Q. I got it.

A. Sorry about that. So we weren't able to -- there's nothing moving the moisture. Keeping the tissue moist, it's very important, because it's very easy to remove the device. With NovaSure, many times what happened, it's almost like the tissue is seared.

Q. Seared?

A. That's right. Yes. So seared to the electrode. It was very hard to remove. Many times, it would pull, coagulate the tissue off.

So retaining the natural moisture is very important. And because of that, we had less tearing and bleeding, which is very important for the procedure, because you -- other issues are not favorable to the patient.

Q. Less tearing and bleeding?

A. That's right. It's always better. This membrane doesn't over heat, because it keeps the moisture to maintain the equilibrium of the surface.

Q. Okay. Now, did all of this factor into your belief that you did not copy the NovaSure?

A. At the time, I really believe and I still believe.

Q. Now, have you prepared -- I'm sorry. Can we show [1232] JTX-32 and JTX-24, just the two charts of the SSED, please.

Okay. What do we see here?

A. This is the safety and efficacy chart approved by the FDA.

Q. So what's the upper one?

A. So the upper one is the Minerva, as you can see, and the lower one is the NovaSure.

Q. Okay.

A. Effectiveness.

Q. And what is the difference in study success rates?

A. This one shows that the Minerva device was significantly higher. And if you are looking at amenorrhea, complete stop of bleeding.

Q. Complete stop of bleeding?

A. Complete stop of bleeding. It's virtually double.

Q. Okay. Now, did this factor into your understanding that you didn't copy the NovaSure at all?

A. I think -- I think this is the other proof that they are different, and it is factored in, because if we would have the same technology, we would have the same result.

Q. I'm sorry. Can you say that again?

A. So if we would have copied the NovaSure, we would have ended up with the same result. Same technology, same process.

Q. You would have expected the same result?

[1233] A. Same result. This is significantly different.

Q. Now, did Minerva's rates stay the same since 2015?

A. I believe they improved.

Q. Okay. Can we see the next slide, please.

Can you tell us what we're looking at here?

A. So after 2015, the last year the FDA agreed that Minerva success rate is 93 percent versus the 77.7 percent of NovaSure and the amenorrhea rate is 72 percent versus 36 percent. I think we additionally proved the point we were making before.

Q. Okay. Now, let's go back to our timeline. We left off where you started Minerva.

And did you at that time, as you were about to found Minerva, did you immediately think to use plasma for specifically endometrial ablation?

A. No.

Q. Okay. Can you look in your binder at DTX-1367, please.

A. One second. Oh, DTX. I'm sorry.

Q. DTX-1367. There are two volumes. Do you have it?

A. I see it.

Q. Okay. And it's probably best if you turn to the second page. There we go.

What is this document?

A. This is a patent for tissue ablation.

[1234] Q. Okay. Is that your patent?

A. This is my patent, yes.

Q. Okay.

MS. ELSON: Your Honor, move to admit.

MR. WOLF: Subject to --

THE COURT: Objection?

MR. WOLF: Subject to prior objection, no objection, Your Honor.

THE COURT: It's received.

(DTX-1367 was admitted into evidence.)

MS. ELSON: May we publish, Your Honor?

THE COURT: Yes, you may.

BY MS. ELSON:

Q. Okay. If we could see the cover of DTX-1367.

And what do we see here, Mr. Truckai?

A. So if we go in the same order before, you can see this is the patent number, which is the '068 patent, and it says it's a tissue ablation system. I'm the primary inventor, and it has been assigned to Hermes innovation, which is my intellectual property holding company. I put many patents into the corporation.

Q. Who owns this patent now?

A. Minerva.

Q. And you're a named inventor; is that correct?

A. Yes.

[1235] Q. Now, did you in your -- let me just ask you generally. So was this patent directed to use of plasma specifically for endometrial ablation yet?

A. No, because this technology is very valuable in many other procedures.

Q. So were you exploring?

A. Exploring, you know, other areas where we can use the technology.

Q. Okay. Now, did you disclose even in this patent the older moisture transport patent, the '520, we were looking at earlier?

A. Yes, I did.

Q. May we go to that, please? Page 2, I believe. All right.

This is -- at the top, this is page 2 of the patent?

A. That's right.

Q. Okay.

A. That's right.

Q. You have it in front of you, too?

A. Yes.

Q. What is all this listed?

A. This is all the patents I found I have to disclose to the Patent Office, to the examiner, to evaluate if this is a new novel technology or not. So I felt even though it's my [1236] own private patent, I felt compelled to disclose it, because they have to see what's out there and make a determination, is it patentable or not.

Q. All right. And what do we see here?

A. This just shows that it was disclosed to the Patent Office, the existence of the '520 patent.

Q. This is the old moisture transport patent?

A. Yes.

Q. Now, if we could go to the abstract. Go back, please. The page, the cover. What is this telling us?

A. It's pretty much describing the invention. It says that you have an enclosed chamber. You are creating plasma within the chamber, which is ionized plasma.

Q. If we could go to Figure 27 of your same '068 patent, please. What do we see here?

A. This technology easily can be used in a cardiac application, where you want to ablate some cardiac tissue responsible for arrhythmia.

Q. Just generally backing up, this is very early just before you founded Minerva?

A. Yes.

Q. And were you exploring different uses of plasma at this point?

A. Yes.

Q. Okay. Can we go to the next figure, 33, please.

[1237] Okay. What do we see here?

A. This is your -- this is the stomach and this is the area which needs to be ablated for eliminate cancerous cells.

Q. Okay. Did there come a point when you began to hone in on the use of plasma specifically for endometrial ablation?

A. I mean, realized the capability of the technology, and we found it's very applicable for ablation and would improve lots of shortcomings of the prior technology.

Q. So you began to focus on endometrial ablation?

A. Yes.

Q. Would you please look at your binder, and DTX -- yes, I'm sorry. So there's a series here. DTX-71. Look at that first.

A. DTX-71.

Q. Take a look. And we've seen, what is it?

A. This is a picture. I'm assuming it's a video.

Q. This is the same video of the plasma formation we've seen earlier?

A. Yes.

Q. Okay. Now, if you could look also, just quickly at DTX-103 to 118. Just flip through those and let me know generally what those are.

A. They are -- seem to be older experimental videos which [1238] were made.

Q. And were these videos you had created of your prototyping?

A. Yes, in our lab.

Q. Roughly, when was that?

A. 2008/2009.

Q. So are these video records of your work that you created in the ordinary course of your prototyping?

A. Yes.

Q. Okay.

MS. ELSON: Your Honor, move to admit, that would be DTX-71, DTX-103 to 118.

THE COURT: Any objection?

MR. WOLF: No objection, Your Honor.

MS. ELSON: All right.

THE COURT: The exhibits are received.

(DTX-71 and DTX-103 to DTX-118 were admitted into evidence.)

MS. ELSON: Thank you.

BY MS. ELSON:

Q. Let's play some of these videos for the ladies and gentlemen of the jury of your prototyping work. Let's show the earliest one, DTX-103.

Okay. First of all, before we roll it, what are we looking at here?

[1239] A. That was one of the early experts where we put a silicone membrane on a tissue. You can see this is under the device. Square box.

Q. This is a box?

A. That's right. So you can see through it with an injecting argon gas.

Q. You're injecting argon gas?

A. Into that chamber and we're looking at how the plasma formation took place, how it reacted, and studying, we have to exchange argon.

Q. Okay. Can we play it?

A. Sure.

MS. ELSON: Go ahead.

(Video played.)

THE WITNESS: You can see, once you started somewhere, that plasma formation, it spreads throughout the entire chamber.

You can see here, you know, you have long plasma. I want to point out, this is plastic, you know, and it

doesn't melt. So it's ablating the tissue. The plasma filaments are hitting the membrane and kinetic energy of the plasma is going to heat generally, heat within the silicone membrane.

BY MS. ELSON:

Q. So this is one of your early prototypes?

[1240] A. Yes. It was very exciting to see how that technology works.

Q. Okay. Could we see DTX-105, please.

What do we see here? And you can ask to zoom in on any part.

A. A squid.

Q. A squid? Okay. And what is it?

A. So this is all the inflow and outflow. You can see how slender is the shaft. And down here, that was the earliest prototype we were able to put together. You can see the silicon chambers. We put electrode inside. We flow argon gas in and out of the chamber.

Q. Did this early prototype have two chambers?

A. That's the separation. One chamber and another chamber.

Q. And can we play or bring up 106, please.

Okay. Before we roll it, what are we looking at?

A. So this is our squid. You can see nobody expended it. We put in this argon gas. I it expended. Vaguely, you can see the electrodes.

Q. Can we play it now?

A. We'll be putting the argon gas. You can see the same plasma formation happening, just like the other one. Not perfect. You can see it's expending and

contracting. There [1241] was no way for us to know how this technology based, because there was no prior art. So I couldn't learn from anybody that experiment. Just like this one, you can see it exploded. So it wasn't a very good day for us.

Q. Is this a setback?

A. I would say so.

Q. Okay. So can we go to DTX-107. And what do we see here?

A. Now, this is another experiment, you know.

Q. Can we just roll this one?

A. Where we lose the two chambers. This is a single chamber now.

Q. So now you're down to a single chamber?

A. That's right.

Q. Okay.

A. So then the expert is thinking, can we make this more uniform in nature. Can we control the plasma formation and ablation process more, especially that depth of coagulation of the tissue.

Q. Would plasma control an issue?

A. I can't even describe the number of issues.

Q. Okay.

A. Exchange rate, voltage, keeping the argon gas pure, you know, during the process. I mean, I can talk a whole day about it. It was a lot of bad days.

[1242] Q. Unfortunately, we don't have a whole day.

So DTX-108, please. And what do we see here?

A. You can see it's resembling a balloon.

Q. Can we zoom in on the tip there. Okay.

A. Again, it's still crude, but now you've got the triangle shape. Unfortunately, it's not transparent, but maybe it has the electrodes inside and the gas outflow for controlling the argon gas.

Q. Okay. Now, if we could go to DTX-109. Okay. Now, before we roll it, what do we see here?

A. That was very exciting. That was one of our better prototypes. You can see now it's a nice triangle shape and the internal electrodes, because the internal electrode is not touching the shape.

Q. So far are we seeing these videos in chronological order?

A. Pretty much.

Q. Yes? Okay. And if we could go to DTX-111, please.

A. Yes.

Q. Okay.

A. This is, again, just showing that you see much finer this solution of plasma, more controlled. This is just a configuration, very close to what we have today.

Q. If we could go to 113.

A. And this is, again, very, very close, but it's still [1243] not the current product. But you can see here, now we have the length, improve the flexure. Everything was worked out.

What you can see here, you put the external electrode on it. Aluminum foil.

Q. Aluminum foil?

A. Yes.

Q. At this time?

A. At this time we used whatever was in the kitchen. We just glued it on and we had a beautiful plasma formation.

Q. What does the final device use in place of the aluminum?

A. We have gold.

Q. Gold. Now, if we go to DTX-115, please.

And what are we seeing here?

A. This is again an experiment with the same device. Actually, you can see here.

Q. And what is the device sitting on?

A. It's liver tissue.

Q. Liver tissue?

A. Yes.

Q. What kind of liver tissue?

A. We use pork or cow liver.

Q. Pork or cow liver?

A. That's right. Porcine or bovine.

[1244] Q. All right.

A. Because it has the closest consistency to endometrial tissue.

Q. Okay. If we could go to 117, please. And were you still having issues at this time?

A. Yes. As you can see, this didn't control very well the process. So move forward, a setback. I mean, years of development.

Q. Right. Let's look at again the final product, the final result of all of your research and development. What do we see here?

A. Now you have the gold electrode on the outside. Inner electrode, all the proportions for plasma formation has been finished.

Q. So this is the commercial device?

A. This is the commercial device.

Q. And did there come a time when you decided to file patents on your own plasma based solution for endometrial ablation?

A. Yes, I did.

Q. All right. If you could turn back to your binder, please.

A. Okay.

Q. And it's specifically DTX-1368 to start with.

A. 13?

[1245] Q. 1368.

A. DTX?

Q. DTX-1368, and just tell me what you see there.

A. I do not have DTX-1368. Oh, I'm sorry. 1368.

Q. Eight.

A. I'm sorry.

Q. And what is it?

A. This is tissue ablation patent.

Q. Okay. And just to deal with them together, if you go to the next one, DTX-1369, what is there?

A. Again, this is our endometrial ablation patent.

Q. Okay. And roughly, when did you file these two patents?

A. In 2009/2010.

MS. ELSON: Okay. Move to admit, Your Honor.

MR. WOLF: Same objection as before.

THE COURT: Overruled. 1368 and 69 are received.

MS. ELSON: Thank you, Your Honor.

(DTX-1368 and DTX-1369 were admitted into evidence.)

BY MS. ELSON:

Q. So if we could just bring up one of the two for now.

So this is DTX-1369. And before we start that.

MS. ELSON: So may I approach the witness, Your [1246] Honor, just to show him something?

THE COURT: Yes, you may.

BY MS. ELSON:

Q. I'm going to bring you, Mr. Truckai, these two documents. What are these? What are the two items I've just handed you?

A. This is the two issued patents describing our technology.

Q. Are these the originals?

A. These are the originals.

Q. From the Patent Office?

A. From the Patent Office. This is like a piece of deed or property.

Q. Thank you.

Now, let's take a look at one of your two plasma formation patents. DTX-1369. And if you could just briefly again walk us through what we see here as far as the number, title, and your name, et cetera.

A. The patent issued. The last digit is 732. The patent was issued in 2013, August 6th. It's describing an endometrial ablation device and system, such as devising the system. It's naming me the primary inventor and one more person. It's assigned to Hermes Innovation.

Q. Who owns these patents now?

A. Minerva Surgical.

[1247] Q. Okay.

A. And you can see that it was filed in 2009, October 26th.

Q. Okay. Go to the abstract, please. And what does this tell you?

A. Pretty much it's describing just like a prior patent. Specifically, an endometrial ablation device.

Q. Now it's specifically endometrial ablation?

A. Yes. It's still having flute-like interior chamber.

Q. If we could go to page 2 of this same patent. Again, what are all of these columns?

A. These are the referenced patents.

Q. That you disclosed?

A. We disclosed to the patented office.

Q. If we could zoom in on that one at the bottom. Once again, did you disclose your old moisture transport technology to the Patent Office?

A. Absolutely.

Q. Okay. Now, let me ask you, why you didn't you disclose the '348 patent that's in this case?

A. I couldn't. At that time, it wasn't in existence.

Q. It didn't exist?

A. No, it did not.

Q. Okay.

A. Years later.

[1248] Q. Okay. Very good.

Now, I'm going to change gears now and ask you just a few questions about Minerva's red/green indicator, so this little red/green item here on the handle.

THE COURT: So why don't we take our morning break before you do that, counsel.

MS. ELSON: Yes.

THE COURT: So let's take ten minutes, ladies and gentlemen.

(The jury was excused for a short recess.)

(Short recess taken.)

- - -

(Proceedings resumed after the short recess.)

THE COURT: Please be seated. If we can get the jury.

MR. WOLF: Your Honor, when do you want to break for lunch today?

THE COURT: I don't know. Sometime around noon. Before, but not after. The jury doesn't listen to you after noon when the clock strikes, so sometime around noon. If at a quarter till, we'll break at a quarter till.

MR. WOLF: We'll still be on cross-examination.

THE COURT: So if your cross-examination is going, then we'll go until noon, but if we're finished with him, we might stop.

[1249] MR. WOLF: I was just trying to figure out if I get to a module at five of, should I flag Your Honor?

THE COURT: That's fine.

(The jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

You may continue your examination.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. So, Mr. Truckai, just to wrap up on the three patents we just walked through collectively, that was DTX-1367, 1368 and 1369.

Are those three collectively, do you mind if I call them your plasma formation patents?

A. You may.

Q. Okay. And does Minerva actually practice its own plasma formation patents in its system?

A. Yes, they do.

Q. Okay. Very good. And these plasma formation patents, do they have anything to do with the older NovaSure technology?

A. I don't believe so.

Q. Okay. But you disclosed the older NovaSure technology in the form of that '520 patent?

A. Absolutely.

[1250] Q. Okay. And, you know, I just want to ask you: You've been accused of copying NovaSure in this case. How do you feel about that?

MR. WOLF: Objection, Your Honor. Mr. Truckai has not been accused of anything.

THE COURT: Please?

BY MS. ELSON:

Q. Excuse me. Minerva, your company, has been accused of copying the NovaSure. How do you feel about that?

A. Speechless.

Q. Does it trouble you?

A. Yes.

* * * *

[1256] BY MS. ELSON:

Q. Okay. I'm going to change topics, Mr. Truckai, and ask you just a couple questions.

[1257] Let's go back to 2004, when the board sold Novacept to Cytyc. Okay?

Now, at the time of the sale of Novacept to Cytyc, what percentage of Novacept did you own personally?

A. Two or two-and-a-half percent.

Q. Two or two-and-a-half percent?

A. Somewhere around there.

Q. Now, how much did Cytyc pay for Novacept?

A. $325 million.

Q. Okay. So if I had my math right, you -- if you owned, let's go with the upper bound, two-and-a-half percent.

You made about 8 million from that sale personally; is that right?

A. That sounds about right.

Q. Okay. So can you tell us, what happened to the other $317 million from the proceeds of that sale?

A. A large portion went to the investors and a large portion went to the people who developed it and worked within the company.

Q. Employees?

A. Technology. The employees, yes.

Q. All right. So was that the remaining 97.5 percent of the sale went to others?

A. Yes, it did.

Q. Okay. Now, one last topic here. Would you please [1258] turn in your binder to tabs PTX-22 and 23.

A. Okay.

Q. Now, what do you understand these to be?

A. If I recall right, it's the video which I shot back in 1996 or around.

Q. So these are screen shots of videos you took in, when did you say?

A. 1996.

Q. Okay. And did you create these videos?

A. I did.

MS. ELSON: I move to admit, Your Honor.

MR. WOLF: No objection.

THE COURT: 22 and 23 are received.

(PTX-22 and PTX-23 were admitted into evidence.)

BY MS. ELSON:

Q. So let's start with PTX-22. And if we could just start, not play it. Just bring it up.

Okay. What is this? This is before you completed your design of NovaSure?

A. Yes. We had nothing. That was just a very rough fabric. We created insulated layers. We had no triangle shape, no handle. We didn't even have a generator.

Q. This is very early?

A. Very, very early.

Q. Okay. So give us some context. What is this? Why [1259] did you create this video?

A. I'm sorry?

Q. Just some context. Why did you create this video? What is it?

A. I had to go to Johnson & Johnson and ask for an investment and they asked me to create a description of the technology.

Q. Okay.

MS. ELSON: Can we play it now?

(Video played.)

BY MS. ELSON:

Q. So --

A. So --

Q. So just very briefly, what are we seeing here?

A. We can see the -- you can see the coagulation in the tissue, so the tissue. Anywhere where the tissue turns white is being killed or ablated. An area, you can see that the depth is being controlled by the center, the center distance of the electrodes.

You can see -- you can have a coagulation where the depth of coagulation goes, and then stops.

Q. Okay. I really only have two questions with respect to this video. Are we watching an ablation using Minerva's device?

A. No.

[1260] Q. Okay.

A. This is -- you can see different, probably different everything.

Q. How many years was it until Minerva's device even existed?

A. Twelve, 13, something like that.

Q. Sorry?

A. 12 or 13, or something like that.

Q. So this is about 12 or 13 years before Minerva's commercial device even existed?

A. Something like this, yes.

Q. And so if I was showing this to someone and telling them or suggesting to them that this is what they would get as a consequence of using Minerva's device, would that be true?

A. No, not at all.

Q. Now, is this using even the NovaSure?

A. No, it's not. It's a concept, a technology concept.

Q. Okay. If we could now play PTX-23.

Actually, can we go back on the years for a moment. You said you did this in '96?

A. That's right.

Q. And you formed Minerva in 2008?

A. Yes.

Q. So how many years was that?

[1261] A. That's about 12 years, but, you know --

Q. You're right, you're right.

A. In 2008, I just did the math.

Q. All right. So PTX-23, please. And if we can just ROLL it.

Okay. I have basically the same question: Are we seeing proof of concept, whatever you call it, using Minerva's device?

A. No.

Q. Okay. And did Minerva's device even exist?

A. No.

Q. This was also '96?

A. Yes, same time.

Q. Was this even using the NovaSure?

A. No.

Q. Did this predate the NovaSure?

A. Way before.

Q. Okay. So if I showed this to somebody and said or suggested, implied this was somehow reflecting a

consequence of what would happen if you used Minerva's device, would that be accurate?

A. Not at all.

Q. Okay.

MS. ELSON: That is the end of my direct examination, Your Honor. Pass the witness.

[1262] THE COURT: Cross-examination, counsel.

MR. WOLF: It will take us a moment to set up.

THE COURT: Yes, that's fine.

MR. WOLF: I promise we will not use all of these documents.

(Pause.)

THE COURT: Whenever you are ready, Mr. Wolf, tell me, and I will turn the microphones on.

MR. WOLF: Yes, Your Honor. Thank you. I'm ready. Thank you.

THE COURT: All right. You may proceed.

CROSS-EXAMINATION

BY MR. WOLF:

Q. Good morning, Mr. Truckai.

A. Good morning.

Q. It is an honor to speak with you, and I speak for everyone in the room when we say we were truly impressed with the history of your development and your contribution to medical science.

I want to talk to you first about the board that you talked about, the board of directors. If I recall correctly, you said board made important decisions with regard to the Minerva product; is that right?

A. The board advises the CEO how to proceed, but the CEO makes the decision.

[1263] Q. The board advises on significant decisions?

A. The board approves significant decisions.

Q. Okay. So let's find out who the board is and who makes those decisions.

And just so we're clear, you are a member of the board?

A. I am.

Q. And you have been the whole time Minerva has existed?

A. Yes.

Q. You've never actually been an employee of Minerva though; right?

A. No.

Q. I asked my question badly because it was a double negative. Have you ever been an employee of Minerva?

A. No. I was always a CEO or board member.

Q. Now, given your other business interests, you don't spend much time on Minerva; is that correct?

A. I spend whatever I have to.

Q. But you don't spend time on Minerva; right?

A. Not anymore. Not on a daily basis.

Q. Yes. And Mr. Clapper is fully capable to run the company in your opinion; is that right?

A. Absolutely.

Q. All right. So you don't need to?

A. I don't.

[1264] Q. All right. Now, from 2008 to the present, Minerva has raised about $125 million of debt and equity; is that right?

A. It sounds about right.

Q. And I want to get a sense of who has been investing and what the role is.

Let's start with a company called Novo Holdings. Are you familiar with that?

A. Yes, I am.

Q. They are a global venture company?

A. They are a very large venture firm.

Q. Could you explain to the jury what a venture firm is?

A. Venture firms, these are inventors who put money into a company for -- in exchange for a certain percentage of ownership in the company.

Q. Okay. So Novo, do they have a board seat?

A. Yes, they do.

Q. Okay. Could you explain how venture companies come to have a seat on a board of directors?

A. They, they come on the board as part of the investment. Very simply, you know, you want X amount of money? Okay. I want X percent of the company, and I also want to be on the board of the company. And it depends on the situation where the company is. You can take the offer [1265] or not.

Q. Right.

A. So most of the time, you know, companies do take those offers, and they bring them on the board.

Q. And sitting here today, roughly, what percentage of Minerva does Novo hold?

A. I have no idea.

Q. Would Mr. Clapper be in a position to know that, do you think?

A. Probably, he could give you a more accurate number.

Q. Okay. Let me ask the question a couple more times then. If you don't know, that's just fine.

Vivo Capital, is that another venture capital company that has invested in Minerva?

A. Yes.

Q. And they're headquartered in Beijing, Shanghai, Taipei and Palo Alto; right?

A. know only the Palo Alto people.

Q. And they have a seat on the board; is that right?

A. They do.

Q. Do you happen to know what percentage of Minerva Vivo Capital owns?

A. I can't give you a very accurate answer.

Q. Okay. New Enterprise Associates is another global venture capital company; is that right?

[1266] A. That's right. One of the largest.

Q. And they have a seat on your board as well?

A. That's correct.

Q. And I will ask the same question, but don't worry. Do you know what percentage they own?

A. Double digit.

Q. Double digit?

A. Yes.

Q. Okay. Versa, another San Francisco venture capital company that has invested in Minerva; is that right?

A. That's correct.

Q. Do you have a sense collectively what these venture capital companies and similar companies own in Minerva altogether?

A. Most of it.

Q. And you and your family personally own about five percent of Minerva; is that right?

A. 4.9.

Q. Now, the goal of the venture capital companies that own Minerva is to sell Minerva as a company to some other big company; right?

A. Not necessarily.

Q. Well, are you familiar with the term liquidity event?

A. Oh, yes.

Q. What is a liquidity event? Could you tell the jury?

[1267] A. A startup has technically two exits, successful exits. One is to go for an IPO, which you go on the stock market. Another way to go is if a larger company can purchase the company, and they pay you

money for the company. So either you go IPO or you go into a merger and acquisition.

Q. These venture companies that own a fair majority of Minerva, they're looking to do one of two things. Either get bought by someone big like Johnson & Johnson or Medtronic, some of the companies that bought your previous startup company, or alternatively go into the stock market and do an initial public offering; is that right?

A. I can't speak for that the venture partners.

Q. But you've had board meetings where they've talked about strategies and what you are trying to do with the company; is that right?

A. We are at the stage where we want to run the business, so we want to be involved with the business, and we want to be -- that's the stage we're at the company.

Q. You would agree it's important to the venture companies that Minerva reaches a liquidity event?

A. I think it's very important for all of us.

Q. Now, this case is about the '183 and the '348 patents. You understand that?

A. I do.

Q. All right. Can we call up on the screen JTX-001, and [1268] that's the '183 patent, what we sometimes call the procedure patent. And you are one of the named inventors; is that right?

A. That's right.

Q. And you would agree that you had a significant role in developing the technology in the '183 patent?

A. Yes, and I'm proud of it.

Q. And in this case you understand that it has been determined that Minerva infringes this patent; is that right?

A. I understand that the decision has been made. The decision has been made.

Q. Understood. Let's call up JTX-002. And this is the '348 patent. And this is what we've been calling the product patent.

You're the lead inventor on that; is that right?

MS. ELSON: Objection, Your Honor. We talked about this.

THE COURT: This is what Hologic has been calling the project patent. That's better.

MS. ELSON: He's calling it the '348.

THE COURT: This is what he's calling it. The witness can agree or disagree. Your objection is overruled.

BY MR. WOLF:

Q. And you're the named lead inventor on this as well?

[1269] A. Hologic put my name on it even though I declared that I'm not an inventor.

Q. We'll get to that, but you are the lead inventor; right?

A. I am not.

Q. Isn't your name the first?

A. I didn't put my name there.

Q. This is a continuation of the application you sold to Hologic in 2004; is that right?

A. Correct.

Q. Okay. Now, you're also aware that it has already been determined that Minerva infringes this patent; is that right?

A. That's my understanding.

Q. Okay. Now, you held up in your direct the pretty -- the PTO issue, what we call ribbon copies of your, your patents with Minerva; is that right?

A. Correct.

Q. All right. And these are the pretty versions of the '183 and the '348 patent.

You characterized these as like a deed in property on direct; is that right?

A. That's correct.

Q. And you would agree that the '183 and the '348 patents are just as much a deed or just as much property as the [1270] patents you held up; is that right?

A. Absolutely.

Q. And you don't mean to suggest that the '183 or the '348 patent are entitled to less respect as deed or property than the patents you held up during your direct examination, do you?

A. No, I'm not.

Q. Okay. You understand it's important for a company to respect the intellectual property of other companies; is that right?

A. Yes, I do.

Q. So I want to spend some time focusing on Minerva's decision-making regarding the '348 patent, the patent we have on the screen.

If we could go to PTX-0114, please. Now, let me tell you.

If at any time -- it's probably going to be much easier if we used the screens for documents, but if at any time you want to see a whole document, they're in the binders next to you, it's entirely up to you, but it probably will go smoother to use, if we're all focused. But, again, whatever you prefer.

A. I'm fine with that.

Q. Okay. Now, this is a letter to you from Mandy Callahan at Hologic in 2014; is that correct?

[1271] A. That's correct.

Q. This "Re" line is request for signature, Hologic inventor declaration; is that right?

A. That's right.

Q. And the last sentence of the first paragraph sat, as a reference, I have also attached a copy of the application as published in February 2014.

Do you see that?

A. Yes.

Q. Let's turn to that application, 42877.

Okay. Now, this is the application that became the '438 patent; right?

A. Yes.

Q. Okay. Now, there were some things -- we can take that down for the moment.

A couple things that have been said earlier in this case that I think might be helpful for you to offer some insight.

When you file a patent application the first time, not maybe later on in continuations, but when you file a patent the first time, that's not public; right?

A. No. Usually, it's six months to a year. I can't determine how the PTO publishes.

Q. Sure. When you first submit a patent, it's quote in secret end quote; right?

[1272] A. I don't know if you call it secret, but I have no access to it.

Q. Right.

A. Not public.

Q. Not public.

MS. ELSON: I'm sorry. I just want a clarification. Do you mean application?

MR. WOLF: The witness answered the question. He understood it.

MS. ELSON: Okay. Confusing.

BY MR. WOLF:

Q. Not public. When you file your application, your first applications, there's nothing wrong about it not being public when you file it; right?

A. I have no control. I can't say it's a problem or not. It's -- you know, the PTO published them on their own timetable.

Q. So you submit an application that's not public, and then at some point later on, it becomes public. The

Patent Office tells the world, hey, here's an application that has been filed. That's your experience?

A. Normal.

Q. Yes. And once an application is published, you can go to the Patent Office's website and look at it. The whole public can; right?

[1273] A. That's correct.

Q. Now, the date -- can we pull that back up, the date of the document? And we see up there publication date, February 13, 2014.

Do you see that?

A. Yes, I see it.

Q. Okay. So on that date, anyone in the world can see that Hologic has filed this application; is that right?

A. Yes.

Q. Now, as of that date, Minerva had not yet even applied for FDA approval for its device; is that correct?

A. They were in the process of completing their FDA filing.

Q. So they hadn't yet filed for FDA approval; is that right?

A. That was about the time. But you can talk to Mr. Clapper.

Q. Fair enough.

Now, on that date, on or about -- let's just round up a little bit, March 2014, in the face of this application, Minerva had at least three choices. It could, in light of the application, it could redesign its product. It could go to Hologic and say, we'd like a license if this ever

becomes a patent, or it can say, we're just going to go ahead and keep doing what doing; is that right? Are those [1274] your three basic choices?

A. I have no idea if anybody besides me was aware. The only time I was aware of that patent, then the letter was sent to me.

Q. Let's talk about that. At the time you get the letter as a member of the Board of Directors, Minerva could have done one of three things and maybe more, but at least these three things.

It could have said, we're going to design around to avoid this problem with the patent issues. We're going to change the way our product is built.

They could say, we're going to go to Hologic and get a license, or they could say, we're just going to take our chances.

What did Minerva do at that point?

A. Personally, I was advised -- I don't recall the discussion we had at the time, but I can tell you my advice would be just move forward because our technology is completely different. And it's very clearly in this patent, it's getting twisted in some way, that you turn a moisture transport system into a no moisture transport system.

Q. I understand your opinion about the patent, but did you communicate that opinion to anyone, or was that what was in your head at the time?

[1275] MS. ELSON: Objection, Your Honor. I just want to make sure we're not treading into privileged communication. Otherwise, it's fine.

THE COURT: So your question is: Did he communicate that with anyone on the board?

MR. WOLF: Right.

THE COURT: And management?

MR. WOLF: That's right. Thank you, Your Honor.

THE COURT: You're welcome.

THE WITNESS: So when I got this letter, it was on my mind.

BY MR. WOLF:

Q. Okay.

A. Because I looked at this, it doesn't make sense.

Q. All right. So now let's go to JTX-005.

And this is what we call a notice of allowance; right?

If we go to 145901, do you see that, notice of allowance? Do you see that document?

A. Yes, I can.

Q. And the date mailed in the right-hand side is 4/27/2015.

A. Yes.

Q. And we see that this was mailed to Hologic, but it is a notice.

[1276] So on this date, on or about April 27th, 2015, the whole world was put on notice that the '348 patent was going to come out; right? That it had been approved by the Patent Office?

A. I was not aware of it.

Q. Well --

A. The only thing I know, when it was published.

Q. You're aware that the notice of allowance is a public document put on the website; is that right?

A. I wasn't aware personally.

Q. Well, are you generally aware with all of your patents that a notice of allowance is the kind of thing that's publicly available?

A. No, I'm not.

Q. All right.

A. I'm not a patent attorney.

Q. I understand. There are certainly people at Minerva whose job it is to make sure you don't infringe other people's patents; right?

A. I assume it.

Q. Yes. So let me ask you, as a board member, in around the time frame of 4/27/2015, when this notice of allowance came out, was there any discussion along the lines of, hey, Hologic is about to get a patent that we might infringe. We need to do something about it, and excluding lawyers at the [1277] board or at management?

A. I don't recall discussion.

Q. The same three choices; right? You could have at this point, now that you know a patent is coming out, you could redesign. You could go to Hologic and ask for a license, or you could just push ahead.

Minerva chose to push ahead after April 27, 2015; is that right?

A. Again, I just can speak for myself. I was not personally aware of it.

Q. And let's go ahead then to August 4, 2015. If we could bring up JTX-2 again, please.

So the way this works is, the Patent Office issues a notice of allowance. There are some formalities. It takes a couple months to get this printed out. Apparently, it takes three months to get this printed. And on August 4th, the patent issues; is that right?

A. That's right.

Q. Okay. And now again, this is -- this is the same month that you launched the commercial launch of your product; is that right?

A. That's right.

Q. And you had three choices again, at least three choices. In the face of this patent, it now exists. You could launch the product and risk infringement. You could [1278] change the design of the product to avoid infringement, or you could ask Hologic for a license.

What did you do at Minerva?

A. So first choice, changing the product, it's virtually impossible. This is a PMA trial. Even the smallest detail, change in the PMA application, it would be a month if not a year delay, which I'm sure you're aware of. So I don't think that we can talk about that, the company was in the position to change the design of the product.

Q. Did you ask Hologic for a license to the '348 patent?

A. I'm not aware.

Q. At or around the time of the issuance of the '348 patent, are you aware of any discussions within the board or within senior management of what to do about the '348 patent?

A. I believe all of a sudden, big challenges.

Q. So you decided at that point that you roll the dice rather than ask for a license and challenge the patent?

A. I don't feel that, you know, we are rolling dice. We felt that we had a very good argument that this patent should have been issued, but, again, it was our opinion or my opinion at the time.

Q. Okay. Now, let's go to claim 1 of the '348 patent. And we've been through this a number of times.

You understood at the time you made that [1279] decision to challenge the patent that if you infringed each of these steps, if your device had each of these things in it, it didn't get you off the hook for infringement if you added other things; right? You understood that, didn't you?

A. Repeat it one more time.

Q. Sure. Okay. Let's break it down. I was trying to get through it. That's my fault.

So we see that there's a device for treating the uterus comprising, an elongate member, an applicator head, a handle, a deflecting mechanism, and indicating mechanism. Those are the bake features of the device; right?

A. Yes.

Q. And you will agree with me that there's nothing in there about whether you do or do not use, for example, argon gas; right?

A. Okay.

Q. Do you agree?

A. I agree.

Q. All right. And you showed those interesting experiments of the balloon and the water and first it

failed, then it succeeded. There's no mention of whether you should or shouldn't have that feature in these claims; right?

A. I don't know how that relates to that.

[1280] Q. All right. Let me go back to my original question, see if this is a better question.

Did you understand as a board that if you did everything in claim 1, it didn't matter if you also had other things in the device. You would still be infringing?

A. I have not done any analysis or formal analysis of the claims of this patent, so I can speak only on my own belief, and my own belief was that, you know, you know, that claim should be challenged.

Q. Sitting here today, do you understand that if you practice all of the claims, all of the elements of the claim, but also do other things, that you still infringe?

Do you understand that?

A. Yes, I do.

Q. When did you come to that understanding?

A. Sometime ago.

Q. So before you made the decision to launch the Minerva product?

A. Yes.

Q. So you understood when you launched that, it didn't matter if you did other things, even if they were really important, good, useful things, that it didn't matter for deciding whether or not you infringed as long as you did what's on the screen right now; right? You understood that when you chose to launch the product?

[1281] A. I still feel that, you know, the right thing to do at the time. Again, just my opinion. It's a challenge because it doesn't make it right.

Q. You didn't agree with the law?

A. I do agree with the law, but the law also allowed you to challenge.

Q. So you decided as a board you would roll the dice?

A. Me, I'm not the board. I'm just a member of the board.

Q. Yes. Mr. Truckai, as I said, none of this is personal. It's company versus company. All of my questions are about Minerva.

You as a board decided that you were going to take a chance and challenge the patent rather than get a license from Hologic or change the design of the product; right?

A. I didn't feel that this is a valid patent, personally.

Q. Now, one more question about your understanding at the time.

There were a lot of questions in your direct about copying. You understood at the time that if you copied what was on the screen or copied that part of the NovaSure device that's reflected on the screen, even if you added new stuff, you're still copying; right?

A. So, you know, let's talk about specifically, what did [1282] we copy?

Q. I'm just asking as a general matter, did you understand that?

A. You know, generally speaking, yes, I understand, but what is it directed and how does it relate to, you know, the Minerva technology? And I'm not trying to be argumentative.

Q. No, no.

A. I'm just trying to understand the points you're trying to make.

Q. If I invent this notebook, and you copy the notebook but then add a great feature so that these things don't pop open as they always do on me, you understand you still copied what I invented; right?

A. I understand.

Q. Even if you come up with a great idea later that may improve the notebook.

A. As long as it's not in the prior art, that's the invention.

Q. Now, you talked about, at some length about the moisture transport system in your direct; right?

A. Yes.

Q. All right. And you said you thought that was essential to your invention, part of your invention, something to that effect?

[1283] A. It's not part and essential. It didn't work without it.

Q. Okay. Now, you, Minerva -- and, again, I apologize. When I say "you," I mean Minerva. I really don't want to make this personal.

Minerva made that very argument to a Court, and that argument was rejected in April 2017; right?

MS. ELSON: Your Honor, this is opening a big door here.

MR. WOLF: Your Honor --

THE COURT: I don't know how else to do this, counsel, so I'm going to overrule the objection. And you may have a continuing objection.

MS. ELSON: Yes, Your Honor.

THE WITNESS: Sir, if you could repeat it?

BY MR. WOLF:

Q. Yes. Let me back up a little bit.

You understand that Minerva made an argument, not to this Court, but to a Court that this claim needed to have moisture transport in it. You understand that; right?

A. Yes.

Q. That was your challenge that you talked about before; right?

A. That's correct.

[1284] Q. Now, in April 2017, that challenge was rejected by a Court; right?

A. Some portion. I believe not everything, but some portion of it.

Q. Well, that particular thing. All of that discussion of moisture transport, that argument, that's not part of claim 1; right?

A. I understand.

Q. Okay. So now as a board, you had this idea that, well, we're going to go ahead and sell the product even though the '348 patent exists, because we think it should include moisture transport, and since we don't

do moisture transport, we can't infringe. Now that's rejected, so what do you do as a board in light of that?

A. There are other ways, you know, to look at the validity of the patent. You can look for patent re-examination or IPR, and I think that's the sensible thing to do, because, you know, the Patent Office is especially focused on this and they're very knowledgeable, more knowledgeable than -- you know, about how to deal with this.

Q. Were there any discussions at the board that you're aware of about the importance of the Court saying, this doesn't include moisture transport, claim 1? Did anybody say, we need to revisit our decision to launch the product [1285] because of what the Court said?

A. The product was already launched.

Q. Fair enough. To continue selling the product as is?

A. We definitely had a discussion regarding the core decision. I felt, you know, personally as a board member, you know, to challenge it to the Patent Office.

Q. So despite what the Court said, you said, we're going to just keep selling?

A. I found out the Patent Office, the people who are very knowledgeable to the case, should be better, whether this claim is valid or not.

Q. Yesterday you weren't here, but we saw a discussion of a design-around with a different measure of, method of attachment of the handle. There was discussion of a pivot point.

Do you remember discussion of a design-around within Minerva?

A. Yes.

Q. Do you know what a design-around is?

A. I do.

Q. Could you explain to the jury what a design-around is?

A. If you can't do it that way, can I change something to make it still work, but it's a little bit different. I would say it's a little bit different.

[1286] Q. So the idea is that there's a patent that I don't want to infringe, but I think I can still make a product without infringing, so I'm going to change the design. I'm going to design around the patent; is that right?

A. That's fair.

Q. It's like if I own this piece of the floor, rather than walk through my piece of the floor, you're going to walk around it; is that right?

A. That's my understanding.

Q. And Minerva looked at a design-around to '348, claim 1; right?

A. Again, I'm not aware of the design-around.

Q. Were you aware that there was a lawyer that was called in to analyze whether the design around infringes the '348 patent?

A. No, I'm not.

Q. Do you know why you were not part of that discussion?

A. I ran two companies at the same time. I'm fairly busy.

Q. So there are some parts of Minerva's activities regarding '348, claim 1, that you are a part of, and others that you are not?

A. I was part of this. Hologic sent me that disclosure, the disclosure statement. I was aware of that. But other effects, I may or may not be aware.

[1287] Q. Now, one more question or series of questions on claim 1.

You understood at the time that Minerva decided to launch its product, that if you infringed claim 1, this language, it didn't matter whether you also had your own patents on your device. You still infringe; right?

A. My personal belief that that patent should have been issued, but, again, it's just my personal belief, and I think the company should challenge it to the USPTO and the PTO should make a determination at the time. That's, again, just my belief, so . . .

Q. I asked a slightly different question.

A. Okay.

Q. Just so I understand what the decision-making was at the board.

You understood it was no defense to patent infringement to say, well, we also have patents on it; right?

A. I don't believe that the board looked at it, that we have a patent. I think the board was in good faith told that, you know, our technology is completely different, and I still believe personally that our technology is completely different.

Q. Okay.

A. And I do understand that, the it written words of this [1288] patent, the claim, and the Patent Office makes mistakes, and, you know, we've got to go and challenge it.

Q. Please try to answer my question. I understand your position.

A. Okay.

Q. But try to answer my question. You understood that it was not a defense to patent infringe. To say, well, we got our own patents on the product, too; right?

A. At that time.

Q. And you understood that the whole time; right?

A. I do understand.

Q. Right. So when you were showing the jury your patents, you weren't trying to tell them, but you got patents, well, you knew you didn't infringe '348, claim 1; right? Wasn't what you were trying to suggest?

A. No, it does not.

Q. Okay.

MR. WOLF: Can we call up DTX-1367, please.

BY MR. WOLF:

Q. You showed us this patent before, do you remember, in your direct?

A. Yes, I recall.

Q. Okay. Can we blow up the first half?

You are the inventor. The assignee is Hermes Innovations, LLC.

[1289] A. Yes.

Q. What is Hermes Innovations?

A. It's my company, and I have my health insurance through Hermes Innovations, and I put intellectual property into the company. And I license it all.

Q. I didn't mean to interrupt. I'm sorry.

A. And I license technologies all from the company.

Q. Right. So you own Hermes; right?

A. Yes.

Q. And Hermes owns the '068 patent?

A. Yes.

Q. And Minerva pays a royalty fee to Hermes to use the '068 patent; right?

A. No, they do not.

Q. They have a license to it?

A. No. In exchange of ownership.

Q. Oh. So you're paid, but in the form of ownership as opposed to a royalty?

A. That's right.

Q. Okay. So let me start over. The '068 patent is owned by Hermes. Yes?

A. Correct.

Q. And Minerva licenses it so that they can, in order to sell their product, they can use the technology in the '068 patent?

[1290] A. That's correct.

Q. And the form of payment you get for that is a part of the ownership of Minerva?

A. That's correct.

Q. Right. So Minerva regularly, in fact, licenses other people's technology to practice and sell its product; is that right?

A. I'm sorry?

Q. I will put some more up there. Let me ask you this: Let me ask it. Minerva licenses other people's technologies in addition to their own patents to sell their product; right?

A. I don't know.

Q. Okay.

A. I know they license mine.

Q. You don't know whether they license others or not?

A. I don't believe so, but I think Mr. Clapper can answer that.

Q. Okay. That's fair.

Now, you would agree that at the time of the launch, you were not qualified, the launch of the Minerva product, you would agree you were not qualified to analyze the claims of the patent and form an opinion about it, because that's not your job; right?

A. That's not my job and I'm not a patent lawyer.

[1291] Q. And you would agree that personally, you're not qualified to go into a patent and analyze the claims and form opinions about it; right?

A. That's correct.

MR. WOLF: Your Honor, may we approach?

THE COURT: Yes.

MR. WOLF: He just answered the $64,000 question. What I normally want to ask next is, so who was it at

Minerva that was competent to decide, that said it was okay to launch the product.

MS. ELSON: It is a foundation issue.

MR. WOLF: No.

THE COURT: No. His next question is, so who at Minerva has said it was okay to launch?

MS. ELSON: Okay.

THE COURT: And then you're going to ask -- so say it again how you're going to do this.

MR. WOLF: So who was it at Minerva that was qualified.

THE COURT: Oh. And then gave the advice to launch?

MR. WOLF: Yes. That said it was okay to launch. I won't say advise.

MS. ELSON: You are saying it's one individual.

THE COURT: Well, that's the who. It could be [1292] five people, four people, three people.

MS. ELSON: Okay.

THE COURT: And if he says a lawyer, then you've got problems. That's the bottom line.

MS. ELSON: Okay.

THE COURT: But he has to answer it truthfully.

MS. ELSON: Yes. But as long as it's not asked. There may have been lawyers involved, but there were also businesspeople. Is there a way to ask it to just exclude any conversations with lawyers?

THE COURT: I think he just names the people, and if he names them and one of them turns out to be a lawyer, we'll take it up then.

MS. ELSON: Your Honor, I would like to have a continuing objection, because we'd like to talk about excluding the two UIT patents. The Exmark decision has a pass knowledge we'd like to show Your Honor.

THE COURT: Excluding what?

MS. ELSON: Those two perforation test patents that we talked about earlier on direct.

THE COURT: Oh.

MS. ELSON: Exmark said expressly, and they should know, you have to show for purposes of the damages that your system is covered by your own patents and that's relevant to damages. If we could just address this later [1293] because they've agreed, we have a stipulation, they've agreed if these patents come in, they've stipulated that we practice our own IT patents already.

THE COURT: We'll take that up later.

MS. ELSON: Okay.

MR. WOLF: I will look at the case. If I'm wrong about the objection, we'll withdraw it. They can deal with it on redirect.

THE COURT: Okay.

MS. ELSON: Or we can just enter the stipulation.

THE COURT: Okay.

(End of sidebar conference.)

BY MR. WOLF:

Q. So I had just asked you, and you would agree that you were not qualified to go into a patent and analyze the claims and form opinions about it; is that correct?

A. No, I'm not.

Q. Who at Minerva, who is qualified to go into a patent and analyze the claims and form opinions about it made the decision or was involved in the decision to release the Minerva product?

MS. ELSON: And, Your Honor. I'm sorry. Objection.

THE COURT: Oh, as previously stated.

[1294] MS. ELSON: That's a different question from what we discussed.

MR. WOLF: I don't think so.

THE COURT: So I just want to be sure. Who at Minerva made the decision to go forward with the product after the patent was published.

Is that the question?

MS. ELSON: That wasn't the question. The question was, who at Minerva who actually did basically an infringement analysis. Perhaps we could just have the question read back.

MR. WOLF: I will break it up into two questions.

MS. ELSON: The first part is objectionable.

THE COURT: Okay.

BY MR. WOLF:

Q. Who at Minerva made the decision to launch the product despite the '348 patent?

A. The board and the management.

Q. Who among the board and management, if any, was qualified to go into a patent and analyze the claims and form opinions about it?

A. None of them. Nobody. None of us are patent attorneys.

Q. So there was not a single person that was qualified to [1295] go into a patent and analyze the claims and form opinions about it who told you it was okay despite the '348 patent to sell your product; is that right?

MS. ELSON: Objection, Your Honor.

THE COURT: Overruled.

MS. ELSON: Can I have a running objection based on Section 289?

THE COURT: Yes.

MS. ELSON: Thank you.

THE WITNESS: Sorry. Can you repeat it?

(The court reporter read back the testimony as follows:

"Question: So there was no one on the board or in management who was qualified to tell you whether or not you infringed '348 patent, yet you went ahead and sold it anyway; is that right?

"Answer: The only thing I can say, I'm sure that management of the company talked to the lawyers who can evaluate.")

THE COURT: All right. I thought it was who on the board or who in management. So I'm going to ask you to rephrase your question.

MR. WOLF: Well, so, Your Honor, just to be clear, the previous question was, who had those qualifications and the answer was no one.

[1296] THE COURT: On the board or in management?

MR. WOLF: In management.

THE COURT: Okay.

BY MR. WOLF:

Q. So there was no one on the board or in management who was qualified to tell you whether or not you infringed '348 patent, yet you went ahead and sold it anyway; is that right?

A. The only thing I can say, I'm sure that management of the company talked to the lawyers who can evaluate.

MR. WOLF: Your Honor, shall we take a break?

THE COURT: This is a good time.

Ladies and gentlemen, I'm going to give you an early lunch. Okay? It's Friday. I feel good about an early lunch. So let's come back at 1:00. Okay? So we're in recess until 1:00.

(The jury was excused for a luncheon recess.)

THE COURT: All right. So if the witness would step down, and you have to go back outside because we're going to talk about your testimony. Okay?

THE WITNESS: Okay.

THE COURT: So I think you're on lunch break.

THE WITNESS: Okay. Thank you.

THE COURT: The rest of us aren't. You are.

MR. WOLF: Enjoy your launch.

* * * *

[1342] BY MR. WOLF:

Q. Just a few followup questions on what we were talking about when we broke and then we will move on to a new topic.

If someone at Minerva had identified what they thought was a serious concern about infringement of the '348 patent, whose decision, one or more people, would it have been to hit the red button, to pull the plug, to stop the press? Who was making that decision?

A. You mean, when you say pulling the plug?

Q. Fair. Let me ask it more formally. It's important to Minerva not to infringe someone's patents; right?

A. That's correct.

Q. Yes. And so if at any point there had been a determination that there was a risk of patent infringement, who, which one or more people would have been the ones that decided, we've got to do something about it, whether it's get a license or not release the product or change the product, whatever it was? Who were the people that would actually decide that?

A. Yes. The board, but they use legal counsel to make that determination.

Q. Let's shift topics now to your role in the early days of the company and the jury was instructed on what a [1343] 30(b)(6) witness is. I assume you don't remember that you were a 30(b)(6) witness for Minerva?

Do you remember you were asked to be the designee on the topic of conception, design, development and testing of the Minerva endometrial ablation system?

A. Yes, I do remember.

Q. So you were speaking on behalf of the company?

A. That's right.

Q. Okay. We call that legal nonsense jargon 30(b)(6). And you were that guy; right?

A. That's right. Yes, I was.

Q. All right. Let's go back to JTX-20, or let's go to JTX-20, which the jury has seen before, but you haven't. And this was a slide deck that you were involved in preparing for a meeting with Hologic; is that right?

A. That's right.

Q. And this was your standard template; right? You presented a similar presentation to J&J and others?

A. As I recall.

Q. Let's go to the next page. That was this mission statement on the next page of the document. That was Minerva's, that's what they were trying to do; right?

A. As I recall.

Q. Next slide.

And that was the attributes you were seeking, [1344] the third slide, the project goal?

A. Sounds reasonable.

Q. Okay. Let's go to the next page. I just want to -- I talked to the jury about this in opening, but I want to now get this officially in the record. This is

Novacept, at least the core team at Novacept in 2009; is that right?

A. Novacept?

Q. Not Novacept. I'm sorry. Minerva.

A. Okay.

Q. I was going to talk about the Novacept. Let me start over. This was the core team of Minerva in 2009; is that right?

A. Yes. And others, and others.

Q. And others? Okay. So we see the board of directors up there, the top, the five people?

A. Yes.

Q. And all five of the board of directors were at one time or another part of Novacept; right?

A. That's right.

Q. All right. Now we see medical advisory board and we see 1, 2, 3, 4, 5, 6 names. What is a medical advisory board?

A. These are physicians who are evaluating your product and they tell you that, you know, this is what they think is needed in the marketplace.

[1345] Q. And how do you decide as Minerva who you want on your medical advisory board?

A. I like knowledgeable people who don't sugar coat it for you and they tell you that, look, you know, this is great, but. So I'm looking for the but. What do we need to fix?

Q. And so these are physicians that you respect to give it to you straight?

A. Yes.

Q. And I want to focus on a couple names. Ted Anderson first. Dr. Anderson has now a relatively prominent role in the community, doesn't he?

A. I believe, I have not kept in touch with him. He was already a very respected physician.

Q. Do you know whether he has a current president title with an organization?

A. I'm not sure. I heard about it. Maybe AGL was going to be one, but I'm not sure, you know, that this is true or not.

Q. Right. In any event, Dr. Anderson is a well

respected --

A. Who's very well respected.

Q. Let's go to the last one. Adolf Gallinat. Another very well respected physician?

A. He passed away, but, yes.

[1346] Q. Fair. But he was a very well respected physician?

A. Yes.

Q. And then Dr. Garcia is actually one of the expert witnesses Minerva will be calling in its case; right?

A. Right.

Q. And she's a member of your medical advisory board?

A. Was part at the time.

Q. Yes.

A. I don't know, I don't know who is the medical board.

Q. But at the time --

A. At the time, she was.

Q. Yes. And then we have Corpora. What does that refer to? I assume that's a typo?

A. Yes. Should be Corporate.

Q. And then we have IP, Jim Heslin, Townsend, Townsend & Crew.

Do you see that?

A. Yes.

Q. Who was Mr. Heslin?

A. Patent attorney.

Q. Is he still Minerva's patent attorney?

A. Yes.

Q. And he was actually Nova's past patent attorney; right?

A. At some point. At the very beginning, no.

[1347] Q. He prosecuted -- he took to the Patent Office a number of the patents we've seen in this case; right?

A. Yes.

Q. He was at Novacept and -- he represented Novacept. Then he represented Minerva; is that right?

A. At the very beginning, you know, I couldn't use Jim at all, also when we started Novacept.

Q. And at some point he became your attorney?

A. At some point.

Q. Okay. Then we have management. I think that's probably self-explanatory, but we see that you and Ms.

Williams and Ms. Morgan were former Novacept folks; is that right?

A. Yes.

Q. Consultants, Mary Edwards. Who was Mary Edwards?

A. Regulatory person.

Q. What do you mean by a regulatory person?

A. Regulatory means dealing with FDA matters.

Q. So you used her as an FDA person at Novacept. Then you chose to bring her to Minerva; is that right?

A. Yes.

Q. We know who Mr. Clapper is. At the time he was a consultant. At some point he became the CEO of Minerva?

A. Yes.

Q. Okay. The Medical Advisory Board, are they [1348] compensated for their services?

A. I think we at the time -- I don't recall precisely, but I think we had formal compensation for them.

Q. You did have formal?

A. Yes.

Q. All right. Let's go to PTX-63. Rather than have them flip in the binder, do you have any objection to what's on the screen?

(Pause while counsel conferred.)

MS. ELSON: What was the question?

MR. WOLF: Just do you have any objection?

MS. ELSON: To 63?

MR. WOLF: Yes.

(Pause.)

MS. ELSON: No objection.

MR. WOLF: All right, Your Honor. Move the admission PTX-63.

THE COURT: Received.

(PTX-63 was admitted into evidence.)

MR. WOLF: Will you publish, sir? Thank you

BY MR. WOLF:

Q. So we see here an e-mail from Michael Regan. Who is Michael Regan?

A. He was the COO of the company.

Q. The chief operating officer?

[1349] A. Yes.

Q. Does that make him number two or number three?

A. He was really doing that day to day, running the company.

Q. So he was running the company on a day-to-day basis. And it's to you, among others.

A. That's correct.

Q. And we talked about Mary Edwards already. Could you remind us who Dominic Filloux is?

A. Vice president of research and development.

Q. And the subject is MAB notes; right?

A. Yes.

Q. All right. Let's look briefly at the notes. Next page. Actually, the third page of the document.

Let's just look at the top two boxes. We say, a topic and a response and action.

Do you see that?

A. Yes.

Q. This is input that your doctors gave you that said this is important for your device. Is that fair?

A. Many times, you know, they said that these are issues. You have to explain to them.

Q. And one of your MAB members said, number scale for cornu measurement is important. If it is under three centimeters, it is almost guaranteed that the device is not [1350] opened enough or is impaled in the wall; right?

A. Yes, I see it.

Q. And that was the advice that physicians were giving you as you were designing the product; right?

A. Yes, but you have to take into consideration, the first time you're talking to these guys, you know, they pretty much tell you what they know. So the physicians are using, as is most of them, are using NovaSure. So once you go into the technology and I explain to them you no longer need this. You don't know what you are going to need to measure regardless of the size of the cornu, and you don't have to, you no longer have to input the cornu. I think they got, you know, pretty much the idea. But that was more like an action that, you know, physicians in the marketplace, you know, they've been conditioned to take a measurement and enter it into equipment.

Q. Respectfully, the answer to my question was: Yes, this is what a doctor would.

A. Yes, but you can't take it out of context. You noted it that, you know, they broke up. Look, you have to enter this in the marketplace. This is important to us right now.

Q. Mr. Truckai, you've attended and participated in FDA meetings regarding the Minerva product; is that correct?

A. Yes, I did.

[1351] Q. And you've been involved in pre-IDE activities as well; is that correct?

A. Yes.

Q. Can you explain to the jury what pre-IDE means?

A. So you go to the FDA, and physicians and other FDA persons who understand the type of product and procedure. They sit down with you and you explain to them how your device is working. You know, they understand, you know, what you're trying to do, and you are trying to give them the information.

You are trying to bring them up with technology, what we're trying to do, how the device is working and what we want to achieve. And this is very important because based on that, you establish later on the protocols, the clinical protocols, how you're going to conduct your clinical trial.

So that's the purpose of that meeting. How are you going to conduct your clinical trial.

Q. Very good.

So let's go to Exhibit 41, PTX-41, please. And this is an e-mail chain at the bottom from Mary Edwards to Colin Pollard, and then from Colin Pollard to Mary Edwards. Keep it blown up.

At the top, it's back to Regan. We'll break this up. Start at the very top of page 2, very top of [1352] page 2, the signature block.

And we see it's from Mary Edwards, and she's identified as the VP of regulatory and clinical affairs; is that right?

A. She was at that time, yes.

Q. Right. What does the VP of regulatory and clinical affairs do?

A. She was responsible to establish the regulatory framework, how we're going to work with the FDA constructing the regulatory file for submission, and she was managing the clinical, overall, the clinical.

Q. And she was good at her job, I assume?

A. She was pretty good.

Q. You brought her from Novacept to Minerva; right?

A. Yes.

Q. Okay. So let's go to the top of this e-mail. It's from Mary Edwards to Colin Pollard. Now, Colin Pollard was at the Food and Drug Administration at the time?

A. That's right.

Q. This is an official communication, or at least one communication between Minerva on the one hand and the United States Food and Drug Administration on the other; right?

A. Mm-hmm.

Q. Yes?

[1353] A. Yes.

Q. I'm sorry. I do this all the time, so it's my fault, but the mm-hmms and the nods, unfortunately, the court reporter can't get?

A. Yes.

Q. This goes without saying. I assume you try to be accurate and honest in all communications with the Food and Drug Administration?

A. You have to be.

Q. Have to be. So she writes, "Colin: I'm under huge fire because I was not able to get answers after almost six weeks. I know it's crazy for you; but not getting any internal sympathy. We have a board meeting on the 20th and fundraising will be dependent on the regulatory plan."

Do you have any idea of what she meant by we have a board meeting on the 20th and fundraising will dependent on the regulatory plan?

A. I can't really can't comment. This is the first time I'm seeing it. I don't know what context she's referring to.

Q. Is it generally true that in order to get fundraising from those large venture capital companies we heard about before, they want to see progress with the Food and Drug Administration towards approval of the product?

A. They want to know what the plan is.

[1354] Q. Right. I'm really hoping that we could touch base for just a couple minutes on the Monday when you return?

MS. ELSON: Your Honor, objection.

THE COURT: Yes?

MS. ELSON: I think he needs to lay some foundation. He just said he hasn't seen this e-mail before, not familiar with it.

THE COURT: Foundation for what?

MS. ELSON: For testifying about this document. It may be appropriate for other witnesses, but Mr. Truckai just testified that he's not familiar with the document.

THE COURT: All right. Mr. Wolf?

MR. WOLF: Among other things, Your Honor, Mr. Truckai was asked the following question:

Was anyone at Minerva -- did you or anyone at Minerva ever believe Minerva copied the NovaSure?"

And he said, No.

THE COURT: Overruled.

BY MR. WOLF:

Q. I'm really hoping that we could touch base for just a couple minutes on the Monday when you return. I fully understand that some of the below might sound new -- but they really are not new questions.

And then number three. The Minerva device is almost dead identical to NovaSure except using plasma energy [1355] (RF).

Now, plasma energy RF, that refers to that balloon you talked all about in your direct; right?

A. Yes. That's assuming that that is what she meant.

Q. And this says that the Minerva device is almost dead identical except for that feature; right?

A. Yes, but, you know, I don't know what before that. You've got to look at it in the context. The clinical trial is pretty much the same, you know, regardless, you know, it's an HTA trial, it's a Minerva trial, it's a NovaSure trial. She was referring from the FDA standpoint, I'm assuming again, but I don't know, that the device trial, which should be engaging, trying to get information out of them, how do you get to run the trial? This is pretty much the same trial, you know, you run many times before. And at the time I remember we were talking about this, this is a PMA. That was like the eighth of the kind at the time. It was eight devices went through the same process.

Q. You would agree that your answer to Ms. Elson might have to be changed in light of this e-mail; right? Ms. Edwards at least thought that the Minerva device was almost dead identical to NovaSure.

A. I -- I don't think so. I'm not sure that she's talking about the way the trial is from the FDA standpoint. You have to look at it from FDA standpoint. It doesn't [1356] matter I'm using -- what do I use. This is from FDA standpoint, conducted go the same trial. You know, you're going to use, you know, the same diary method, evaluation. I mean, I didn't see anything new here from the FDA. I think that's what she's referring to, but, again, I can't comment.

Q. All right. Let's go up one more e-mail in the chain. Keep the whole thing blown up.

Now, you can just keep the whole blown up. I think everybody can read it.

From Colin Pollard. Then we see the official FDA address. Food and Drug Administration at Human Services.Gov.

Do you see that?

A. Yes.

Q. He's writing to Mary Edwards. He says, I'm sorry. I was away last week on vacation. I hoped my last e-mail to you would help, but I will find some time to talk to you tomorrow even if it's late any day. So the FDA is trying to be cooperate you've with you; right?

A. I can't comment. I don't know what the discussion was. If that was the only conversation they had at the time, I can refer to the written words.

Q. All right. Now, next at the top, Ms. Edwards forwards this to Michael Regan; right? Do you see it to Michael [1357] Regan, she forwards this e-mail exchange?

A. Okay. I see it.

Q. Yes. And she writes: Mike, interesting. We're getting better response from FDA than from our own advisory board. Talk to you tomorrow.

Do you see that?

A. Yes.

Q. To your knowledge, did Mr. Regan or anybody else ever say to the FDA at any time, you know what we talked you it was dead identical? We were wrong. It's not dead identical.

A. I don't know. Even in the response, the prior e-mail, there's no response. You can see a short answer,

and then the next thing, we had a better response, so I'm confused, you know. I mean, I don't know what she's referring to. I don't know we got a great response, you know. After weeks, there's no response, then a little blurb and she called it a great response. I just want comment.

Q. You understand that to infringe a patent, you don't need to copy it. You can infringe a the patent even if you didn't even know about an old product; right?

A. Of course. If you don't know anything about it, you are looking. This is a prior art.

Q. I'm sorry. That was a bad question. Patents are like deeds. I think you used that before; right?

[1358] A. Yes.

Q. If I infringe someone's patent and I didn't even know about it, I'm still liable for infringing; right? It's not something I have copy or anything to be an infringer; right?

A. I understand.

Q. But copying is a big deal for whether you're a willful infringer; right?

A. I understand.

Q. And what you thought about your similarity to a product that's patented, that's a big deal; right?

A. We didn't feel that we have any similarity beyond the point, which was public knowledge. Those devices, you know, had existed before. So that was our belief.

Q. Let's move on to PTX-601. Is that objected to?

MS. ELSON: It's okay.

MR. WOLF: Thank you. If we could put 601 up on the screen.

THE COURT: Has 601 been received?

MR. WOLF: It has, Your Honor. Well, it hasn't.

It's no objection from Minerva.

THE COURT: Okay. Can you move?

MR. WOLF: I move to admit 601, Your Honor.

THE COURT: 601 is received. Okay.

(PTX-601 was admitted into evidence.)

[1359] BY MR. WOLF:

Q. We see in this e-mail, it's from Michael Reagan, the person we were just talking about, your COO; is that correct?

A. Correct.

Q. And it's to a number of members of your advisory board, including Dr. Ted Anderson; is that right?

A. Yes.

Q. And these were folks on your Medical Advisory Board; is that right?

A. That's right.

Q. And you're on this as well. Is that right?

A. That's right.

Q. You look under the first full paragraph, last sentence. We were fortunate to have Dr. Gallinat proctor these cases which helped tremendously with the new user learning curves.

Do you see that?

A. Yes, I do.

Q. You would agree as we were talking about before, doctor Gallinat's opinion is well respected?

A. Yes. I think his is pretty good, what he used to do.

Q. Yes. And then we have procedural observations, and just a few examples. The second bullet: We are investigating methods to minimize tip profile, that [1360] referring to the handpiece of the device; right?

A. The tip of the device.

Q. Of the handpiece, the tip of the handpiece?

A. This is the plug formation.

Q. Just so we understand what we're talking about, whichever product we're talking about, this is the handpiece; right?

A. Yes, but this is talking about the very tip, this one.

Q. Understood. It's a piece of the handpiece? It's a part of the handpiece?

A. There's a big difference between a handle and a tip. This is specifically stating the tip profile, which is that was the important thing, because I'm not taking the handle and put it into the uterus. The only portion that goes into the uterus --

Q. I am delighted to hear that that is not the case. But just so we're getting our words and our nomenclature straight, when I say handpiece, do we all understand that that is what I'm referring to?

Does that make sense?

A. That's a handpiece.

Q. Yes. And so he's talking there about a part of the handpiece?

A. He's talking about the most important part of the device, which is the tip. He's not talking about the entire [1361] device. He's talking about a portion of the device.

Q. All right. If we look three bullets down, a suggestion was made to use dot scale for feedback on cornu-to-cornu measurement. Additionally, it might be helpful to increase the resolution of the reading scale.

Again, talking about a part of the handpiece; right?

A. Yes.

Q. And there we're talking about this measurement right here; is that correct?

A. It's not a measurement. It's an indicator. But that's what we're talking about.

MR. WOLF: Your Honor, may I approach?

THE COURT: The witness?

MR. WOLF: No. You, Your Honor.

THE COURT: Yes, you may.

(Sidebar conference held out of the hearing of the jury as follows.)

MR. WOLF: So, Your Honor, you will recall we had a discussion I guess on Friday about this. I envision major patent infringement disputes.

THE COURT: This is from Anderson.

MS. ELSON: This is the one I think Your Honor excluded.

MR. WOLF: With invitation to revisit, lay a [1362] foundation. And I just went through this document and established who Mr. Anderson was, what his relevance to the company was and some of the bullets refer to the handpiece, so I think I've laid the foundation now to get his response.

THE COURT: Just let me look at it again.

MS. ELSON: Okay.

THE COURT: This is from Anderson. Your objection is?

MS. ELSON: My objection is that this is now -- it's four-and-a-half years before the patent ever existed, so how can it be relevant to a recklessness or state of mind with respect to what is covered by the patent. Copying in the instructions was covered by the patent. It wasn't filed. It wasn't published, nothing.

This is going to overlap into the '183, which one could, you know -- that one is out. Willfulness is out on the '183.

THE COURT: But you're saying that this covers both.

MR. WOLF: Yes. We just saw on direct, she went through claim 31 of the original patent that talked about moisture transport.

MS. ELSON: Let me be clear. These bullets are separate from that statement. Just because he's commenting [1363] about things about the handpiece doesn't mean -- it's ambiguous. We don't know because they never deposed Dr. Anderson. It's unclear.

THE COURT: All right. He was never deposed by either side.

MS. ELSON: Correct.

MR. WOLF: Correct.

THE COURT: All right.

MS. ELSON: There's no foundation linking this to.

THE COURT: I'm sorry. I think it goes in.

(End of sidebar conference.)

THE COURT: So, Ms. Elson, when we get to the appropriate time, if you would lodge your objection.

MS. ELSON: Yes. Yes, Your Honor.

THE COURT: Okay.

MS. ELSON: For the record, I object now.

THE COURT: Now? Let's wait for a question first.

MR. WOLF: Your Honor, we would ask to admit and publish Exhibit 58.

THE COURT: Okay. And your objection?

MS. ELSON: We object, Your Honor, for all the grounds we just discussed.

THE COURT: All right. This is Exhibit --

[1364] MR. WOLF: PTX-58.

THE COURT: PTX-58 is received.

MR. WOLF: Thank you.

(PTX-58 was admitted into evidence.)

MR. WOLF: Could we go to PTX-58 and start with the section we were just on. The second page, please.

BY MR. WOLF:

Q. Mr. Truckai, just to be clear, this is the e-mail we were just looking at from Mr. Reagan to, among others, seconds line, Dr. Anderson; is that right?

A. Yes.

Q. And if we scroll up to the response, please. And this is from Mr. Anderson to Mr. Reagan; is that right?

A. Yes.

Q. It says, looks good. How long after treatment is the hysterectomy done? Have you looked at hysterectomy about two to four weeks after treatment? There is going to be further tissue devitalization after the initial burn and it would be good to examine at what that looks like.

He says, I have one sort of global question. I envision major patent infringement disputes for this device versus NovaSure. How is this being dealt with or how do you plan you will be able to deal with it?

Do you see that?

A. Yes.

[1365] Q. You were on an e-mail that responded to the list. Scroll up. And this is from Mr. Reagan to Dr. Anderson, and cc'd on that was Mary Edwards, who we talked about before, and then Dr. Skalnyi.

So now Mr. Reagan, your COO, writes, thanks for your comments on our peri-hysterectomy series. The hysterectomy is typically done just following the ablation treatment. The uterus is sent to pathology within the hour. We have not done any two to four-week post treatment hysterectomy. Discussions to date with FDA indicate that we won't be required to do delayed hysterectomy cases. Then he said, regarding the patent position, we have been closely working with counsel on this matter since the inception of the company and will continue this approach on our design choices.

Do you see that?

A. Yes.

Q. So Mr. Reagan told Dr. Anderson at that time that you were aware of the risk of patent infringement, right?

A. That was Dr. Anderson's opinion, not our opinion. Dr. Anderson didn't know all the details, so, for example, he didn't understand using know meter versus pressure sensor. So, you know, his general comments here is not understanding, you know, what we were doing at the time.

Q. You weren't surprised when Hologic sues you in 2015, [1366] were you?

A. I was somewhat surprised.

Q. Even though members of your Medical Advisory Board were telling you there were global patent problems?

A. But they have no information about that, how we're doing.

Q. Let's go to Exhibit JTX-15 and specifically let's start with page 146893. It's about 15 pages before that. 146893.

All right. Focus on claim 31. Do you recall talking about this?

A. Yes, I do.

Q. So this was a claim in your original application all the way back in 1998; is that right?

A. Yes. They filed the patent application with that claim.

Q. And you agreed that there's nothing in this claim, in claim 31, that says anything about mesh or moisture transport; right?

A. At the time, it was our belief that we can get a broader claim.

Q. All right. So in 1998, when you filed this application, all that discussion you had about how moisture transport was what you invented, you thought you invented more than that as represented in claim 31; right?

[1367] A. We thought we can have a broader claim.

Q. So you thought just like Hologic thought with claim 1 of the '348, that you could get a claim without moisture transport; right?

A. Correct.

Q. Okay. Let's go to 146906. We see -- actually, can we see, go down, please. One more page.

That is your signature?

A. That's correct.

Q. And you, although the printing is not great, you're agreeing that you hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true letter further, that these statements were made with the knowledge that willful false statements and the like are so made and are punishable by fine or imprisonment or both.

A. Yes.

Q. And you understood at the time that the Court signed the declaration, you were attesting that you

believed you were the original first inventor on the subject matter of claim 31; right?

A. The entire patent.

Q. Including claim 31?

A. Yes.

[1368] Q. This was all before Hologic bought Novacept; is that correct?

A. Yes.

Q. So Hologic bought Novacept at a time when you had written a sworn statement that you believe that a patent could issue on a claim that didn't require moisture transport; right?

A. Based on the information I had at the time.

Q. I understand that. But Hologic bought the patent, bought -- spent a lot of money on it. $325 million. We agree that's a lot of money; right?

A. Yes.

Q. And a big part of the deal was the intellectual property; right?

A. Yes.

Q. And if the patents weren't useful, they never would have made the deal; right? No one is going to buy a company with a cool product if other companies can come in and just knock it off because there's no patent protection; right?

A. That's correct.

Q. A big part that makes your company potentially attractive to others is that you have your own patents; right?

A. That's correct.

[1369] Q. If you didn't have patents, if someone could come in and knock off Minerva, your company wouldn't be worth anything, or be worth very little; right?

A. Correct.

Q. And so when Hologic bought this patent, they had your sworn statement that you didn't believe that moisture transport was an essential part of your invention; is that right?

A. Again, I believed, but later on I mentioned the Patent Examiner brought it up, this is not going to go because there is prior art. So that's why we canceled the claim.

Q. Understood. You came to change your mind, I guess, but at the time, it wasn't like you told Hologic, look, these patents only apply to moisture transport and you are not going to get protection against someone that uses something different like an argon balloon, did you?

A. Well, no, because the technology is so different anyway.

Q. Now, we've heard in this case about supposed confidential information shared with Hologic.

As far as you know, all the conversations with Hologic and Minerva, Minerva didn't share any confidential information; right?

A. Shared a ton of confidential information with Hologic.

Q. You remember that Minerva's talks with Hologic at [1370] board meetings around 2009 or 2010 involved nonconfidential discussions; is that correct?

A. In 2009. I can't recall 2010, but 2009, yes, it was not confidential.

Q. To the extent there were any board meetings in 2010, they also involved nonconfidential information; right?

A. I can't recall. Honestly, I can't just tell you what information I had in 2010 with the board.

Q. I believe not to go to the deposition. Let me just ask you. You are not aware of any confidential information shared with Hologic in 2010 board meetings?

A. 2009 and 2010, I don't really know.

Q. All right. So let's shift our attention to 2011. Mr. Truckai, by 2011, Minerva's EAS design, and by EAS, referring to this product?

A. That's right.

Q. Minerva's EAS design is completed in all material respects; is that correct?

A. Pretty much.

Q. Well, I want to be clear. It was completed in all material respects; right?

A. I don't know what changes they have done after. But from my standpoint, it was pretty complete.

Q. Now, you showed the will map of the AAGL 4. Do you remember that in your direct?

[1371] A. Yes.

Q. All right. And you showed -- I don't think you talked about it, but you showed that Minerva had a booth there; right?

A. That's correct.

Q. Let's call up PTX-602. This will be used as a demonstrative, Your Honor.

If we go to the top of the screen, this is from Mr. Clapper to a series of folks, including you. You're on the last "to" lines.

A. Yes.

Q. The subject is Minerva at the 2011 AAGL meeting in Florida.

Do you see that?

A. Yes.

Q. It says, attached is a brief recap of this week's AAGL meeting, and a short slide show so you can see the team in action. Dave?

Do you see that?

A. Yes.

Q. I think the jury probably knows it. Just in case, the AAGL, that's the Super Bowl of your industry?

A. Yes.

Q. I probably just committed a trademark violation by using that term.

[1372] Let's go to the next slide. So you showed -- that's the cover of the slide presentation.

Next slide. I think that's the slide that you had showed with Ms. Elson with the various booths colored in; is that right?

A. I believe so.

Q. Right. The next slide. That's your booth; right?

A. That's the Minerva booth.

Q. Right. And we see in that booth -- is there a laser pointer? We see in that booth, we see the device; right? The handpiece device?

A. Yes.

Q. And then there's the controller?

A. Yes.

Q. And just so we're clear, by this time, the handpiece, everything was completed, so this is the final design; right?

A. Or very close to the final.

Q. Okay. And then we have this board. So let's go to the next slide. This shows us what the board said. It gives us the procedure time; right?

A. Yes.

Q. It tells us, no pre-treatment?

A. Yes.

Q. Tells us about the sealing balloon.

[1373] A. Yes.

Q. Tells us about the silicon array?

A. Yes.

Q. The plasma energy design?

A. Yes.

Q. The diameter?

A. Yes.

Q. And there's a note basically say, you're not yet approved to sell; right?

A. That's correct.

Q. Right. And just to get back to this in a second, but just so we're clear, as a medical device developer, you are allowed to develop a device without any fear of patent infringement; right? It's when you start selling that you get at risk. Isn't that your understanding?

A. That's not completely accurate, because I wouldn't have been able to find the company, patent infringement. I cannot go with a clear conscience. When investors give money to me, I'm not looking, they give it to the company. They I've it to me. So I have to do a better job if there's any chance for patent infringement.

Q. I asked a very bad question. What I was trying to say is, legally speaking, you're allowed to, for example, do your clinical trials, and that's not patent infringement, right, because patent infringement is only if you are [1374] selling the product commercially?

MS. ELSON: Objection, Your Honor.

MR. WOLF: I'm just trying to explain what the bottom of that is. I can move on.

MS. ELSON: Trying to elicit a legal opinion.

MR. WOLF: I can move on.

THE COURT: Well, you're going to withdraw the question?

MR. WOLF: Yes.

THE COURT: Okay.

MR. WOLF: You understood that you are allowed to do clinical research with your product, and even if the product would infringe when you start to sell it, it's not infringing doing clinical research; right? That's your understanding?

THE COURT: Overruled.

THE WITNESS: It's not very practical, because end of the day, you know, if you have patent infringement or not, you know, you've got to go in front of the investors and tell them that, you know, I think we have a problem or not. You're not going to be able to raise any money. It's not very practical to do -- spend the money on a clinical trial and you know you are infringing. It makes no sense.

BY MR. WOLF:

Q. I don't want to dig too deep in, I don't think it [1375] matters that much, but sometimes companies will develop a product to launch after a patent expires; right?

A. Maybe. I don't know.

Q. So when the '348 patent expires, anybody can do anything they want. That's the whole point of the patent deal; right?

A. Yes.

Q. So you can develop prior to the expiration of a patent and wait to sell until the patent expires. Then you can do whatever you want; right?

A. Yes, but in this case, when they launch the product, that wasn't an issue. I mean, you know, it hit us out of the blue.

So if you are looking, I believe this started in August, everything was prepared by us. They got the FDA approval prior to that. You know, everybody felt very good about it, the boards, me. You know, said go ahead, launch the product, you know, and, you know, here you go a few weeks later, you know. A, the patent comes out. That's the first time that we're way, you

know, that it's potentially an issue. And, you know, Hologic should have let us know. Not until November of that year in November of 2015 that you have an issue with it.

Q. Are you aware of the fact that your CEO told folks right at the time of the launch, or excuse me, right at the [1376] time of the lawsuit that they had been anticipating a lawsuit for at least six months?

A. You know, I have to tell you, when I did SurgRx, I anticipated the lawsuit at any point in time. If you are not anticipating, you know, you're not doing your job as a CEO.

Every single company I started, I always believed, even at Novacept, I anticipated that somebody is going to sue us. Johnson & Johnson or somebody for reason or no reason, they're going to sue you.

Q. When did you personally first come to think that Hologic might sue you if you launched Minerva's product?

A. When the patent got issued and we were aware of it, so that's one. And really, I was hoping it's not going to happen, but Hologic, you know, filed the lawsuit.

Q. So you weren't aware of other activities or other information in the company prior to then anticipating Hologic's lawsuit?

A. No.

Q. Okay. That wasn't shared with you?

A. I mean, we knew that you filed the patent, but, you know, I didn't know that the patent is, you know, until it issued, I wasn't aware that it was an issue.

Q. Okay.

A. So by the time we launched the product.

[1377] Q. Were you monitoring Hologic's patent portfolio?

A. So my practice, you know, every, you know, six months or so, I go and I check, you know, what's going on. Otherwise, you know, if -- the person I'm looking at my patent is getting issued, I'm getting the notice of follow on or rejection. So I partly don't have to do that.

Q. I just asked another bad question because I used a pronoun that wasn't clear.

Does Minerva check on or keep track of Hologic's patent portfolio?

A. I have no idea.

Q. Shifting gears and we're wrapping up, Mr. Truckai, and I appreciate your patience very much.

You would agree that the cavity integrity test was one of the reasons for NovaSure's success; right?

A. That's one of the reasons, yes. But actually, if you -- believe it or not, we did the clinical trial without it.

Q. The cavity integrity assessment was very important to the commercialization of NovaSure; right?

A. It was very important.

Q. It was very important; right?

A. I would say it's important. Important, yes.

Q. Is there a reason today you're saying important and at your deposition, you said very important?

[1378] A. You know, the applicator had as important a task. You know -- what is the ethical, what is the safety? How do you want to split it?

Q. The cavity integrity assessment is a safety feature that you have to have; right?

A. Many products doesn't have it on the market right now.

Q. It was your view that you have to have it. Otherwise, the physician doesn't have feedback if the device is correctly positioned; right?

A. Correctly positioned and having a perforation is two different things.

Q. Well, let me just ask the question. You would agree that it's a safety feature, you have to have it. Otherwise, the physician doesn't have feedback that the device is correctly positioned; right?

A. I will agree with you only if you are talking about perforation, because the purpose of the it is did you perforate it or not? So it's nothing that has to do with the position. It's not fully opened and it's still passing the perforation detection and it's okay. It's not a safety concern. It's an ethical concern. I mean, it doesn't make -- I don't know if it makes sense. I'm not trying to avoid the question. I'm just trying to tell you, the positioning of the device is ethical. Perforation, it's a safety.

[1379] Q. Can we just agree that, for however you want to slice that apple, it's a safety feature that you have to have?

A. It's an important safety feature.

Q. And you would agree that Minerva's UIT, its uterine integrity test, is an important feature?

A. It is an important feature.

Q. And it's an important safety feature?

A. It's an important safety feature.

Q. And you would agree that without the UIT, the Minerva EAS really isn't the system; is that correct?

A. I'm sorry?

Q. You would agree that without the UIT, the Minerva EAS really isn't a system; is that correct?

A. I would not agree with that. I think it would be a significant and a safer system, but it still could be as effective as it is today. Again, it's a safety issue, not ethical issue.

Q. It's a must-have feature?

A. It's a good-to-have feature.

Q. It's a reason why in your deposition you called it a must-have feature and you're calling it a good feature today?

A. No. The way you slice it. One is safety, another one is ethical.

Q. I think just one more document. You would agree, I [1380] think, already that Minerva always strives to give truthful and accurate information to the FDA; is that correct?

A. Absolutely.

* * * *

[1385] REDIRECT EXAMINATION

BY MS. ELSON:

Q. So in the meantime, just for context, Mr. Truckai, now, Mr. Wolf raised the Hologic and, in

particular, Cytyc [1386] had filed an application that eventually issued as the '348 patent.

Are you aware of that?

A. Yes.

Q. Okay. And when was the first --

MS. ELSON: Can we pull up in the meantime, Jim, I'm sorry, PTX-0114, just while you're looking for that other one.

Oh, I missed it. So if we go to the back of the application that was attached to this cover letter. Okay. There's some claims.

You were sent these claims. And the first time, however, that you saw this application was when you received it. And if we could go back to the cover letter.

MR. WOLF: Your Honor, I just ask counsel be reminded, this is redirect, not cross.

THE COURT: Overruled.

BY MS. ELSON:

Q. So you --

MR. WOLF: I meant in terms of leading questions.

THE COURT: Okay. I understand.

BY MS. ELSON:

Q. Did you receive this on November 21st, 2014?

A. Yes, I did.

[1387] Q. Okay. So when was the first time you became aware that Cytyc Hologic had filed an application that later we learned issued as the '348?

A. I think about that time.

Q. Okay. And were you traveling at this time?

A. Yes. I was in Europe.

Q. What, to the best of your recollection, when did you actually sit down and read this and respond to Hologic?

A. I think in December sometime.

Q. Would that be December 2014?

A. I don't remember. I mean, I don't remember. Around that time.

Q. Around December 2014?

A. I remember that, you know.

Q. Okay. And this was the first time that you became aware of this application; is that right?

A. That's correct.

Q. Now, when patent -- counsel went on and on about how the world was given notice that the '348 application had been filed.

Does the world receive notice the minute an application is filed or do you have to go to the website to actually proactively look what's filed?

A. You have to look.

Q. Okay. So the Patent Office posts when something is [1388] filed and published; is that correct?

A. It's very random. You never know when they're going to publish.

Q. But when they do, they publish it on their website; right?

A. That's right.

MR. WOLF: Your Honor, same objection.

BY MS. ELSON:

Q. But you would have to go to the website to find it?

A. Absolutely.

THE COURT: I understand your objection. It's leading.

MR. WOLF: Yes, Your Honor. And these questions don't matter, but when we get to more significant ones, I want to note my non-waiver foundation.

THE COURT: Okay. So noted.

MR. WOLF: Thank you, Your Honor.

THE COURT: You may continue, counsel.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. So, again, as far as you were ever personally aware of this application in the files is when Hologic actually sent it to you?

A. I had no way to know that they filed. I didn't, I didn't even go and look.

[1389] Q. Right. But when they sent it to you, you became aware; is that correct?

A. Oh, yes.

Q. All right. And when they sent it to you, and here's the cover letter, did they say a word about, hey, Mr. Truckai, we're concerned about infringement? Anything about that?

A. This is the letter.

Q. That's the letter. It doesn't say anything about infringement, does it?

A. No.

Q. In fact, what it says in the Re line, it's a request for signature.

Do you see that?

A. Yes.

Q. So where they were just saying, hey, Mr. Truckai, we'd like your signature on this.

MR. WOLF: Your Honor --

THE COURT: Now at this point. Leading.

BY MS. ELSON:

Q. What were they asking for, Mr. Truckai?

A. They wanted me to sign this document.

Q. What was it?

A. That I'm the inventor on this patent.

Q. Okay.

[1390] A. When I reviewed the patent, you know, I realized that I'm not the inventor of this patent.

Q. Okay. And anything in here indicate to you that they had even the slightest concern about infringement?

A. No.

Q. Okay. Any time before Hologic filed its lawsuit, to your knowledge, did they ever come to Minerva and say, hey, and this is for the course since Minerva was founded and they learned about you. In the course of the seven years, did they ever say a word about any concern?

MR. WOLF: Objection, Your Honor.

THE COURT: I'm asking if there was any concern about infringement expressed to Minerva.

THE WITNESS: Not I'm -- I'm sorry.

THE COURT: You can argue your case in closing argument. Okay? This is a direct examination, so you have to be -- I don't have to tell you. The objection is sustained.

MS. ELSON: Thank you, Your Honor.

BY MS. ELSON:

Q. All right. So you received this request for signature, and did you respond?

A. Yes, I did.

Q. Okay.

MS. ELSON: Can we bring up PTX-06. Okay.

[1391] BY MS. ELSON:

Q. And let me see here. And I apologize. Can we go back to the prior exhibit? The letter? I forgot to point out, do you have it there, Hologic's PTX-114? If you could look at that and go to the claims at the very back.

A. This is the --

Q. PTX-114. Hologic's PTX-114. This was attached to the cover letter.

A. PTX-114.

Q. Correct.

A. 0114.

Q. 0?

A. Oh, 0114.

Q. And if you could just go back to the claims at the very back of the attached patent application, the Hologic test. Flip to the last page.

Are you there?

A. Yes.

Q. Do you see the claims at the end of the patent? Excuse me. The application?

A. That are canceled?

Q. Claim 8, for example?

A. Claim 8?

Q. Yes. Do you see that?

A. Yes.

[1392] Q. Okay. Do you see the element, an indicator mechanism? Do you see that element?

A. Yes, I have.

Q. Okay. That's easier on the screen?

A. Yes. I didn't bring my glasses.

Q. So was this the first time you had ever seen an indicator mechanism as one of the claims in this family of patents?

A. Yes. That is the first time I've seen it.

Q. Okay. And then you responded, and if we could bring up, again, sorry, PTX-106.

So if you could go to the top and zoom in there. It's a little hard to read.

Okay. And this is -- what is this? What are we looking at?

A. This is a letter that I wrote to Mandy.

Q. And who is Mandy?

A. That person that sent me that request.

Q. Was she with Hologic?

A. Yes.

Q. And so you're responding to this letter that they sent in November attaching the application?

A. That's right.

Q. Okay. And what's the date on there?

A. 12/19/2014.

[1393] Q. In substance, what were you saying to her? Let's start with the upper part, starting with following will all the way down to the use of -- before the use of mechanical spreaders?

A. I stated --

Q. What are you saying here?

A. That I reviewed what they requested. I reviewed the document and that I, in good faith, I can't claim that I'm, you know, the inventor, you know, on this application. And it's not my invention. I mean, I don't want to put my name on an invention if I'm not an inventor.

Q. And why didn't you think this was your invention?

A. First thing, I knew in the past, they have -- oh, I'm sorry. I was aware that, you know, other devices like this on the market. So, you know, I didn't file a patent application because it was already there.

Q. Now let's just highlight starting with the use of mechanical spreaders. Go down the through the rest.

Okay. And can you just read that first sentence highlighted there, Mr. Truckai?

A. The use of mechanical spreaders for indicating the width of a uterus was well-known at the time that we filed the application describing uterine measurement.

Q. Go ahead and read the rest?

A. I would love it and such devices and I incorporated [1394] such features into the device that I described in the application. At no time have I ever considered the use of the mechanism indicator mechanism disclosed and for the first time now claimed in the application to be an invention.

Q. Did Hologic follow up and ask you to send them some prior art on the mechanical spreaders?

A. No, they did not.

Q. If we could go to now -- if we can pull up the one where the pat even office -- I'm sorry, the applicant amended the claims, rejected the claim. Maybe we can remember from yesterday.

So after this, did the Patent Office reject all the claims in this application?

A. I think so.

Q. Okay. If we can find that rejection. Perhaps, ladies and gentleman of the jury, remember this. All the claims were rejected, and were they rejected based on one of your earlier patents?

A. That was the prior art.

Q. All right. And then you provided prior art to Hologic for the indicator mechanism?

A. That's right.

Q. Okay. And there we go. So all of these claims -- can we go to the examiner's response, paragraph 15 to 16, just [1395] to remind the ladies and gentlemen of the jury.

So after you responded to Hologic, there we go, the Patent Office rejected the claims of this patent as unpatentable. Is that your patent, the '880?

A. That's right.

Q. Okay. In view of King.

Do you see that.

A. Yes.

Q. All right. So after you told them this wasn't in your invention and you thought mechanical spreaders were old, are you aware that the Patent Office rejected all of these claims?

MR. WOLF: Your Honor --

THE COURT: Your objection is?

MR. WOLF: Leading.

MS. ELSON: I'm asking if he's aware that the examiner rejected all of these claims.

THE COURT: I'm afraid we're never going to get finished with the testimony unless it's more or less leading.

MR. WOLF: All right, Your Honor.

THE COURT: Okay. But I don't want to discourage you from objecting when you believe that it's appropriate, but under the circumstances, and given the subject matter, I don't think that it's improperly leading [1396] the witness.

MR. WOLF: Understood, Your Honor. Thank you.

BY MS. ELSON:

Q. So did you become aware later that the Patent Office had rejected all of these claims?

A. Yes.

Q. Okay. And is that based on, is that your '880 patent?

A. That's correct.

Q. And is that based on the King reference?

A. That's right.

Q. Okay. If we go to paragraph 16.

And do you see hear the Patent Office said King discloses a uterine device, including an indicator mechanism.

A. That's right.

Q. So do you believe the Patent Office agreed with you, that King was right about this is all old and unpatentable?

A. I believe so.

Q. As far as what Hologic sent you?

A. Absolutely.

Q. I won't go into what happened after that, but we can talk about that later. So let me move on.

And let's see. Now, did you consider Minerva's red/green indicator to be again an improvement on the old gauge?

[1397] A. It wasn't that important to us.

Q. Okay. Now, if we could pull up PTX-41. Okay.

Do you remember this one, which is the one Mr. Wolf showed you from Ms. Mary Edwards, who at the time was Minerva's VP of regulatory with the FDA.

A. Yes.

Q. Okay. Now, this was sent, if we could go to the top, in July 2010; is that correct?

A. Yes.

Q. Okay. Now, do you recall when the '348 patent, which is the only one at issue for willfulness, did this exist yet?

A. No.

Q. Okay. And when did it issue?

Do you recall?

A. 2015, August something.

Q. Okay. And as far as -- just look at the subject line, because -- did you say something earlier about this had to do with clinical trials?

A. Clinical testing.

Q. And what did we see here in the subject line? Could you highlight please regarding endometrial ablation, just the word regarding endometrial ablation trials?

A. Yes, because the budget and the way you conduct in the cloud is very much related.

[1398] Q. Now, was Ms. Edwards, did she as far as you know have any technical degree?

A. No.

Q. What was her specialty?

A. Regulatory.

Q. Does the FDA have, just at a high level in general, its own regulatory scheme what they are talking about whether things are similar or not?

A. Also, they have their own language.

Q. And does that -- does the similarity have to do that you go to the same test, test the device in the same way?

A. I assume, but, again, I wasn't on this e-mail, but that's the assumption, you know.

Q. Okay. And if we could go down to the part that Mr. Wolf pointed to towards the bottom, item three, specifically. Let's highlight that. There we go.

Now, here she's saying the Minerva device is almost dead identical to NovaSure and she's talking about the trials; is that correct?

A. It is, because it's a global -- meaning you insert it blindly. You don't see where it is. You have to position it, and how do you test it?

How are you going to conduct --

Q. How do you test it?

A. Yes.

[1399] Q. Did she tag on, except using plasma energy RF?

A. You have to disclose to the FDA that, you know, the energy type is different.

Q. And is that, have you that that is what makes it different from the NovaSure?

A. Yes. And the agency's view about it. We did a demonstration for them. We showed them how different we are.

Q. Okay. So she's saying identical, but it says accept using plasma energy; is that correct?

A. Correct.

Q. Is that your plasma formation array?

A. Yes.

Q. If we go further down, one last thing here?

A. Just one thing I would like to point out.

Q. Sure?

A. We did show the working unit to the FDA. It's not just, you know, Colin Pollard, but others, so it wasn't like we tried to hide. We showed them, this is the device.

Q. Absolutely. And then if you go down to page 3691, let's go town to, this is the bottom of the e-mail chain, so this is the context for the conversation. So let's just take a look at that at the subject line.

MR. WOLF: Your Honor --

BY MS. ELSON:

[1400] Q. Again, it says regarding endometrial ablation trials; is that correct?

MR. WOLF: I understand the interest of moving this along, but this is pure testimony --

THE COURT: No. I understand. Some of it is and some of it isn't, Mr. Wolf.

MS. ELSON: I will just point out two more things, Your Honor. I won't comment.

THE COURT: Okay.

MS. ELSON: Okay. Go ahead. I'm sorry.

THE COURT: Well, I will talk to you about it later, but I'm going to overrule your objection right now, Mr. Wolf, and we'll go from there. But I can't make your objection for you either when she crosses the line, so I'm expecting you to make your objection. But I understand that it's not fair to Ms. Elson for you to be jumping up and interrupting the testimony all the time. So we'll just have to play it by ear.

Go ahead, Ms. Elson.

MS. ELSON: Thank you.

BY MS. ELSON:

Q. Do you see where it says, the first line, could you answer a couple of quick questions? Do you see that sentence?

A. Yes.

[1401] Q. Again, it says, we don't have to highlight that, but can you highlight regarding endometrial ablation trials?

A. That's right.

Q. Okay. And then just regarding endometrial ablation trials.

A. Yes, I see it.

Q. And then a little further down, the next paragraph, can you highlight pivotal trial? What is a pivotal trial? If you know?

A. Yes, I see it.

Q. Okay.

THE COURT: The question is, do you know what it is?

THE WITNESS: Yes, yes, I do know the pivotal. This is the final PMA clinical trial which you are going to submit to the agency if you are involved.

BY MS. ELSON:

Q. Okay. Is this in the context, this whole conversation? Does it appear to you to be in the context of how do you test the device?

A. Yes. I'm painfully aware what was the subject at the time. I can explain if you want.

Q. So I just want to make sure that her comment to Mr. Colin Pollard was regarding testing?

A. That's right.

[1402] Q. You don't need to elaborate?

A. Okay.

MR. WOLF: Your Honor, I don't know whether to laugh or object.

THE COURT: I think laughing is plenty fine. Okay?

So you may continue, Ms. Elson.

MS. ELSON: I'm only trying to move this along.

THE COURT: No, I know that.

MS. ELSON: Okay.

THE COURT: It's a precarious dance. Friday afternoon. I understand that.

MS. ELSON: Thank you.

THE COURT: So continue.

BY MS. ELSON:

Q. Okay. PTX. Let's move on from this one. PTX-0058. Okay.

This is that e-mail that Mr. Wolf showed you from a Dr. Ted Anderson.

If we could go down to where it says, I have one sort of global question.

THE COURT: So excuse me, counsel.

MS. ELSON: Yes.

THE COURT: What exhibit number is this.

MS. ELSON: PTX-0058.

[1403] THE COURT: Thank you.

MS. ELSON: Okay.

BY MS. ELSON:

Q. Do you recall talking about this earlier with Mr. Wolf?

A. Yes.

Q. Okay. Now, at the time, if you look at the date, at the time, did the '348 exist?

A. No.

Q. Okay. So do you think Dr. Ted Anderson was talking about the '348?

A. No. It was almost four years later.

Q. Okay. And as far as the patents we're talking about in this case, was it only the '183 that existed?

A. That's correct.

Q. Correct?

A. That's correct.

Q. Yes. And there's no allegation that Minerva willfully infringed the '183 patent in this case; is that correct?

A. Not at all.

Q. Okay. So just globally, if we could bring up, just JTX-42.

Okay. Now, if we could zoom in on the top, please.

So before I ask about this specifically, [1404] Mr. Wolf showed you some old power points and things from 2009; is that correct?

A. Yes.

Q. All right. Now, you do recognize what this is?

A. Nondisclosure agreement.

Q. And can we highlight this? This is between Minerva and Hologic.

A. Yes.

Q. Okay.

A. I'm sorry.

Q. And it's dated January 6th, 2010; right?

A. Yes.

Q. So when he was showing you and asking you about information conveyed prior to this, the NDA was not yet in place; is that correct?

A. Because I remember in November of 2009, it was a harmless, you know, nonconfidential, but that had been eight years.

Q. Okay. It was after that that Minerva revealed a lot more information to Hologic?

A. Yes, that would be correct.

MS. ELSON: All right. Thank you very much. No further questions.

* * * *

[1414] THE COURT: Please be seated, ladies and gentlemen.

You may continue your examination of the witness, Mr. Wolf.

MR. WOLF: Thank you, Your Honor.

If we could call up PTX-114, please.

BY MR. WOLF:

Q. This was the request for you to sign the patent application?

A. Yes.

Q. And to be clear, this is an application that tied all the way back to your work in 1998?

A. Yes.

Q. And at the time, November 21st, 2014, you had finalized your design for the Minerva product; is that right?

A. Yes.

Q. So you knew that if you signed this application, you would be signing onto a claim that your product that you had been working on for five years infringed; right?

A. It wasn't my thought, sir.

Q. You knew that you would infringe the claims that were in this application; right?

A. I felt, I wanted to see, you know, I've never been in the situation and I thought we had prior art, but I asked, [1415] you know, to sign something, which I knew that it shouldn't be valid.

Q. So the claim was rejected, but then it was amended. It issued and the product infringes; right?

A. The patent was issued.

Q. So let's go to. PTX-481. I just want to be clear. This is the document where Ms. Edwards says, the Minerva device is almost dead identical.

Two questions. You would agree with me that dead identical is not language in talking about clinical studies or -- that's talking about the product; right?

A. I cannot tell you what she meant by dead identical, but, you know, the two devices are not dead either.

Q. The second question is: You said, and I just want to be clear, that you had showed the FDA, at the time you were describing dead identical, I think you said, the whole final device; isn't that right?

A. Whatever stage the device was, which I cannot tell you besides this. Minor modifications.

Q. PTX-58, please. This is a document where it says, one of the members of your Medical Advisory Board, Dr. Ted Anderson said, I have one sort of global question. I envision major patent infringement disputes.

Do you see that?

A. Yes.

[1416] Q. Counsel asked you about dates.

A. Yes.

Q. Do you remember?

A. Yes.

Q. Just to be clear, the application, original application was filed in 1998, and by this time, it was public; right?

A. Yes, but nothing to do with claims. It was issued later. At the time I didn't know when it was going to issue.

Q. It's important for Minerva to make sure they don't infringe other people's patents; right?

A. If I know about it.

Q. Right. And you're aware that almost every medical device company on earth has a group that specifically is tasked with tracking the patents of their competitor; is that right?

A. I don't know. The company, I'm not sure. We do have a team. I don't think that we have the resources. But Mr. Clapper can answer that.

Q. Last question. JTX-42. You were asked about the date of this document.

Do you remember that?

A. Yes.

Q. Just so we're clear, you would agree with me that the [1417] 2011 AAGL conference occurred after the date of this document?

A. Yes.

MR. WOLF: No further questions.

MS. ELSON: No further questions, Your Honor.

THE COURT: All right. Ladies and gentlemen of the jury, do you have any questions of this witness?

You may step down, sir.

(Witness excused.)

* * * *

[1418] . . . EUGENE SKALNYI, having been duly sworn as/affirmed as a witness, was examined and testified as follows . . .

MR. BISH: Your Honor, may I approach?

[1419] THE COURT: Yes, you may.

DIRECT EXAMINATION

BY MR. BISH:

Q. Good afternoon, Dr. Skalnyi.

A. Good afternoon.

Q. Are you employed at Minerva Surgical?

A. Yes, I am.

Q. What's your title?

A. I'm serving as vice president of medical affairs.

Q. Can you tell the jury a little bit about yourself, starting with your education?

A. I was born and raised in Eastern Europe in the country of Maldova. I went to medical school. I graduated with a degree in medicine. Went through my specialty training in obstetrics and gynecology, subsequent to which I went through additional training in Germany in advanced endoscopy, followed by Stanford and some additional training in Sacramento.

Q. Stanford University, is that in California?

A. It's in California.

Q. So, sir, are you a medical doctor?

A. Yes, I am.

Q. Are there other medical doctors in your family?

A. Yes. Exactly. A family of physicians. My wife is an OB/GYN. My sister is an OB/GYN. Her husband. It's a [1420] number of gynecologists in the family.

Q. Now, sir, when you first moved to the United States, can you tell the jury what you did professionally?

A. Well, we moved to the U.S. in about 1998. Came in as refugees. I couldn't work as a physician right away. And we had to support our family, so I had actually two jobs. I was delivering pizzas initially and selling cars. But then subsequently, I obtained a position at Stanford teaching advanced endoscopy.

Q. Advanced endoscopy, what is that?

A. It's basically conduct of minimally invasive procedures and we were teaching basically technique, or how to con duck those procedures to gynecologists and surgeons that exhibited interest in this type of procedures.

Q. We've been talking a lot about endometrial ablations in these proceedings. Can you explain how what you were doing at Stanford relates to ablation?

A. Ablation back then and still is, the only one available was the rollerball ablation, which is a minimally invasive procedure. So that was a part of the curriculum that was taught at the course. So the rollerball procedure was taught to the doctors.

Q. You say rollerball?

A. Yes. It's rollerball.

* * * *

[1425] Q. How do you know that?

A. Any time you make a change to a medical device that has a material impact on the outcome of the procedure, certain documentation has to be filed with the FDA, where FDA has to be advised that this device is actually different than the device that was originally approved, and even though this is the case, most likely additional clinical resources are required.

And everything that was filed so far indicated that the generation to generation of this device is really equivalent to the one that was there before.

Q. Okay. Now, let's fast-forward. And now you're at Minerva Surgical; right?

A. Yes.

Q. And how many Minerva procedures have you observed?

A. Hundreds.

Q. And have you trained doctors on the use of Minerva?

A. Yes, I did.

Q. Now, so you're very familiar with the Minerva product; is that right?

A. I am.

* * * *

[1428] Q. That's from the doctor's perspective. Now, what about from the patient's perspective? In your experience, what is better about the Minerva device than anything else, any other ablation device?

A. Well, I will tell you this. That we see that -- we get a lot of reports that the amount of both intra and post-operative discomfort or pain is somewhat less. But I think the important ones are those that we

actually can actually touch, and basically say, okay, we know that for a fact, and success. Basically, the objective of the procedure, to make sure that you're successful.

This particular technology allows for the highest success among all when comparing to any device that was developed in history of ablation. Rate of amenorrhea. This is by far the most desirable outcome as indicated by the recent research of over 1200 women, that indicated that the ultimate outcome for them is to have amenorrhea, meaning no bleeding whatsoever.

So Minerva produces by far the highest rate of amenorrhea. Patient satisfaction is extremely important. [1429] Patients in our study show one of the highest, if not the highest rates of patient satisfaction. But I think the most important one often not looked into and not recognized is understanding why these procedures are performed in the first place and the true objective of end ablation is actually avoidance of hysterectomy. That's why these procedures are done.

So the question should be: In the long term, are his's avoided or not? And when you look at the outcome, at the clinical data coming from the FDA, outcome of Minerva procedure produces seven times outcomes when comparing to NovaSure when it comes to rate of hysterectomy at three years post procedure.

Q. And how does that compare to the other devices, like Thermachoice or HTA?

A. It's even better.

Q. Or Her Option. I'm sorry. What was that?

A. It's even better.

MR. BISH: Your Honor, I don't know how long you want to go this afternoon before we break. I'm at a transition point. I'm happy to keep going.

THE COURT: I think you should.

MR. BISH: Okay. Great.

THE COURT: I'd like to go for a bit longer.

So we've tipped our hand. We're going to let [1430] you out a little early. Mr. Bish let the cat out of the bag, but I'm the one that's going to let you out early.

MR. BISH: I'm not taking credit for Your Honor.

THE COURT: Mr. Bish, keep going.

MR. BISH: Can we get DDX-10, slide 5. Slide 5. Yes.

BY MR. BISH:

Q. Now, again, we've talked a lot about the success rate already. I know we've beaten the 77.7 number to Beth. Sir, what are the SSED rates for the Minerva?

A. Well, we've conducted two FDA clinical trials, and when you look at the success rate in the first clinical study, it was 91.8, so basically almost 92 percent, and 93 percent in the second study. When you look at the rate of amenorrhea, meaning complete cessation of bleeding, it was 66.4 percent in the Minerva treated patients in the first study, and 72 percent in the second.

Q. And if we can pull up JTX-24 at page 21 just very quickly.

What do you see here, Doctor?

A. Basically, these are the numbers. In the SSE document, which is the summary of safety and

effectiveness document, and this is a document that's published by the FDA.

* * * *

[1482] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Monday, July 23, 2018
8:30 o'clock, a.m.

VOLUME 6

BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[1654] . . . DAVID M. CLAPPER, having been duly sworn/affirmed as a witness and testified as follows . . .

* * * *

[1655] DIRECT EXAMINATION

BY MR. POPLAWSKI:

Q. Please introduce yourself to the jury and tell us where you work.

A. My name is Dave Clapper. I am the president and CEO of Minerva Surgical.

Q. A name we've heard from time to time. When did you start work at Minerva?

A. In May of 2011.

Q. What are your responsibilities as the president and CEO of Minerva?

A. I'm responsible for a variety of things, including setting the strategy for the company, filling out the organizational chart, particularly at the top level of the senior management team.

I'm responsible for finalizing the product line, financing the company, et cetera, et cetera.

Q. How many years did you work specifically with endometrial ablation devices?

A. I started in 1990s.

Q. How many years have you worked in the field of medical devices?

A. Over 40.

* * * *

[1682] Q. All right, Mr. Clapper. We're going to switch to another topic, and that is Minerva's communications with Hologic.

Did Minerva have any communications with Hologic when it was developing Minerva's product?

A. Yes.

Q. And when did that first happen to your knowledge?

A. I believe the first communications were in the fall of 2009.

[1683] Q. And how did that happen, sir?

A. Well, this is a, one of my unemployment periods, and I met with Csaba. He described to me what his plans were and his vision for Minerva Surgical. And we talked about the project and its financing requirements and getting to clinical trials and what his vision, again, of what -- how the product could potentially improve patients with AUB.

And we left and a couple days later, I thought about the project, and I suggested that since we had had such a good, you know, collaboration with Cytyc, it was then, of course, part of Hologic, but many of the people still worked there, that I suggested, you know, it just seems like the right thing to do to contact them and tell them right from the start exactly what you're up to, the project you're working on, your vision of why it could be an improvement over all the other ablation product that are out in the marketplace with your hope, because you're going to need money down the road, that they could get excited about this and say, hey, this looks great. We'd like to work on this with you.

Q. When did you first reach out to Hologic?

A. In the fall of 2009.

Q. And did you understand Hologic to be interested in talking further to Minerva?

[1684] A. Yes. Right away. Yes. Immediately.

Q. And what happened next?

A. So we had a short meeting at a surgical conference that took place, I believe the third week in November, and after that, they went away and thought about it, and we had gotten back in contact with each other and decided that we wanted to then

kind of formalize the effort of talking to each other, and we signed a nondisclosure agreement so that we could from that point on disclose everything about the product.

* * * *

[1693] Q. Now, let's move forward from January 6th, 2010. Did you share any confidential information of Minerva with Hologic under this confidential nondisclosure agreement?

A. Of course.

Q. What did you share, sir?

A. Everything that was on the list that we talked about earlier. We shared with them not just, here's the device and here's the controller. We took the cover off the controller in our laboratory, showed them the inner workings of the controller and how it worked. We had the engineers discuss and lecture their engineers on, at least a person from R&D, on how the system worked. We answered all of their questions about everything from plasma formation array, which takes a little while to understand, as everybody in this room can attest to now, through all the steps of the procedure and how they were different from the Minerva device because at the outset, it looks like this is a very similar device, but when you go through the steps, it's very different. But, yes, everything that they asked [1694] questions about, we gave them the answers.

Q. Did you share any financial and business information of Minerva's with Hologic?

A. Yes. We shared with them information that we don't even share with our own employees.

Q. All right. Would you go to, and I have to ask you about this first before we get a publication request.

A. Okay.

Q. So would you go to DTX-0642. And I will wait until you're there, Mr. Clapper.

A. I'm there.

Q. What is this document, sir?

A. This is a presentation, one of a series of presentations that were made to Hologic over the course of our discussions with them. This was -- it looks like this was made in September of 2012.

MR. POPLAWSKI: Your Honor, move to admit it into evidence.

MR. WOLF: No objection.

THE COURT: 642 is received.

(PTX-221 was admitted into evidence.)

MR. POPLAWSKI: Thank you, Your Honor.

BY MR. POPLAWSKI:

Q. Mr. Clapper, we've now published. What is the date of this presentation by Minerva to Hologic?

[1695] A. September 24, 2012.

Q. Okay. And was this a presentation of confidential Minerva information?

A. Some of it was confidential. Some of it was not.

MS. ELSON: But, yes, it included confidential information.

Q. And who gave this presentation to Hologic on September 24, 2012?

A. I did.

Q. Was that in person between you and Hologic?

A. I believe so, yes.

Q. All right. Let's talk about who those persons were at Hologic. Who at Hologic did you share this presentation with in person?

A. As I recall, it was Russell Layton and Shacey Petrovic.

Q. And at the time, what was Mr. Russell Layton's position with Hologic?

A. I believe he had just come out of a research and development position and was at this time working as a director of business development.

Q. At Hologic?

A. At Hologic. Mm-hmm.

Q. Shacey Petrovic. At the time of this September 24th, 2012, presentation, what was her position with Hologic?

[1696] A. She was the general manager of the surgical division, which included endometrial, the endometrial ablation product, NovaSure.

Q. All right. Now --

A. And vice president.

Q. Thank you.

Can you describe the circumstances under which you shared this September 24th, 2012, presentation with Ms. Petrovic and Mr. Layton?

A. Well, this was in one of the ongoing series of meetings and presentations. As you recall, we met with them in 2009, in 2011, in 2012, so here we are

again, and we're giving them a presentation that's formatted similar to the earlier presentations we gave, but as we're going through this, we're giving them a detailed update on where we're at.

Secondly, I point out, this presentation is a guide. Okay. So throughout this presentation, for example, when we would talk about the technology, we would break, go into the laboratory with them, and actually demonstrate the controller and the device. In fact, on this particular day, we actually went in and had them do a simulated endometrial ablation in a large piece of beef liver, where they actually walked through all the steps of the procedure.

Q. Was Minerva's intellectual property shared with [1697] Hologic?

A. Yes.

* * * *

[1702] Q. Now, what happened after Ms. Petrovic and Mr. Layton visited Minerva and received all of this information back in September of 2012?

A. They were very pleased with the meeting and told us that they were excited to go back to Boston, where the Hologic's headquarters are, and they were going to meet with Rob Casella, who set was the president of Hologic, and try to put together a creative deal whereby they would acquire Minerva.

Q. The --

A. This was a pretty exciting day at little Minerva Surgical.

Q. Did Minerva, in fact, receive any offer from Hologic to acquire the company?

A. No. We didn't hear anything. We thought -- when they left, said they'll get back to us in a week or ten days. It was two weeks, three weeks, four weeks. Finally, we prodded them. Hello, are you going to get back to us? And they [1703] did, finally.

* * * *

[1705] A. I tried to lay out the series of major events, not all of the communications and events that took place between our first contact in the fall of 2009 and, you know, the November 2015. So on this blue line, it shows we met 2009, 2010. We signed the nondisclosure agreement so we could really go to work collaboratively, sharing all kinds of information.

We met again in 2011. It's not on here, but we met in 2012, where we went through the presentation that we just looked at.

In 2013, five Minerva patents issued, so things are humming along. We're, you know, conducting clinical trials. Life is good. And then August 13th, we had other, you know, teleconference calls/meetings.

So this is the way that I and the senior management teams in Minerva looked at the relationship. We had everything going along great here.

What we didn't know is on the redline above it.

[1706] Q. All right. Would you talk about this redline that you prepared which starts with the word Hologic?

A. Okay. So this is the disappointing part. While we are sharing with them everything about our technology, our financial status, everything about the company, our view of the market, clinical investigators, detailed information on how our clinical trial was going after we treated 30 patients, 60, 90,

and so on, what we didn't know that was in August of 2013, secret to us -- remember, this nondisclosure agreement we signed was mutual, where we could both share confidential information, but secret to us, in August of 2013, Hologic filed for the '348 patent.

Q. All right. And that '348 patent issued in August of 2015?

A. Yes, I believe it was the first week of August 2015.

Q. And then we're here with a lawsuit in November of 2015?

A. Right.

* * * *

[1729] CROSS-EXAMINATION

BY MR. WOLF:

* * * *

[1736] Q. I'm talking as a general concept. What did you understand --

A. Putting this aside.

Q. Did you know --

A. A company is representing certain things and warranting certain things -- the company, an individual, et cetera.

Q. And you understand that -- you understood in the context of this document that Hologic was entitled to rely on your reps and warranties and that they did so in signing the document; is that right?

A. That's a good assumption.

Q. Let's go to 3.9(e), so just to be clear, before we go on, this is Article 3. These are horribly paginated documents, but this is Article 3.

A. Yes.

Q. Okay. So let's go to 3.9(e). And this is a rep and warranty that Novacept made to Hologic in 2004; is that right?

A. I have to read it.

(Pause while witness reviewed exhibit.)

THE WITNESS: Okay.

BY MR. WOLF:

Q. So you made the representation in 2004 to Hologic that Novacept has no present knowledge from which it could [1737] reasonably conclude that Novacept's own intellectual property and any intellectual property licensed to the company under the company licensed intellectual property, are invalid or unenforceable; right?

A. At the moment this was signed, yes.

Q. Yes. In 2004?

A. Yes.

Q. Now, there has been some testimony in this case about Novacept's awareness of a product called Vesta in 1995.

You would agree with me that to the extent that Novacept knew of something before 2004, it was telling Hologic, we don't think this invalidates any patents you might have or get; right?

A. Yes. I didn't know anything about the Vesta product whether we sold them. I had heard of it. I had

never seen it. I had never held it in my hands. I had never seen a picture of it. I don't know anything about it. I saw it last week though.

Q. Right. Certainly, Hologic was entitled as a matter of signing this agreement with you to understand that it was not Novacept's position that Vesta invalidated any IP; right?

MR. POPLAWSKI: Objection, Your Honor. Calls for speculation and what was not in the minds of what was set.

* * * *

[1778] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Tuesday, July 24, 2018
8:48 o'clock, a.m.

VOLUME 7

BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[1858] (The jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

You may proceed, Mr. Bish.

MR. BISH: Thank you, Your Honor. Minerva offers the deposition testimony from Ms. Whitney Parachek, which, as a reminder, as you've heard, Ms. Parachek

was the head of sales for Hologic's surgical division in 2015 and 2016.

We're going to start with Ms. Parachek's February 23rd, 2016 deposition.

THE COURT: You may proceed, counsel.

(The videotaped deposition of Whitney Parachek was played as follows.)

* * * *

[1862] "Question: You had conversations at Hologic that Minerva is a startup company; right?

"Answer: Yes.

"Question: That they have limited funds; right?

"Answer: Sure.

"Question: And if -- if Hologic is successful in preventing sales in the near term after launch, Minerva won't be bought and won't be a competitor; right?

"Answer: Those discussions have been had.

"Question: And so that is the strategy at Hologic, right?

"Answer: What is the strategy?

"MR. BISH:

"Question: To prevent Minerva from having any traction in the market in the very near term so that it can't be bought and will go under, right?

"THE WITNESS: Our strategy is -- our strategy is to focus on selling our products and continuing to partner with our customers that we have for the past 14, almost 15 years.

"Question: And you've had conversations that Hologic's strategy should be depriving Minerva of sales in the near term so they can't go bought and they go under; right?

"Yes or no? Have you had those conversations?

[1863] "Answer: We've had those conversations.

"Question: And I asked you earlier what were the factors that caused you in 2014 to perceive Minerva as a formidable competitor?

"Do you recall what factors you had in mind?

"Answer: I believe I answered that that was -- they were going to be a new competitor, as a new competitor coming to market.

"Question: And did it impact your opinion that several of the individuals at Minerva had -- were amongst the inventors of NovaSure?

"Answer: Did it impact my opinion?

"Question: That they were going to be a formidable competitor?

"Answer: Yes. I mean, I knew that Eugene and Dave Clapper had had success in startups:

"Question: Including Novacept; right?

"Answer: Including Novacept.

"Question: And they were amongst the inventors of NovaSure; right?

THE WITNESS: Eugene and Dave were part of that team.

"Question: Which gives them credibility in the market; right?

"Answer: Yeah, I think that -- yes, they had

* * * *

[1871] "Question: Can you give me a rough approximation as to the number of customers who were exposed to the videos after Minerva's launch?

"Answer: No.

"Question: Fair to say in the hundreds?

"Answer: I would have no estimate, I don't know."

(End of videotaped deposition.)

MR. BISH: Thank you.

Minerva now offers the video deposition testimony of Tom O'Neill.

As a reminder, Mr. O'Neill was the president of the surgical division in the 2015 time period, and the deposition is dated April 25th, 2017.

(The videotaped deposition of Tom O'Neill was played as follows.)

"Question: Do you recall anything about how the circumstances by which Minerva was first introduced to you?

"Answer: As near as I can recall -- and my memory is not always perfect at my age. But as near as I can recall, it's just that there was a competitor coming into the space. And it was -- the GEA space hadn't had a new competitor in quite some time.

"Question: But from the outset, you conveyed to [1872] your team that the goal was to not let them sell even one product. Right?

"Answer: No, I don't recall that at all.

"Question: Because you knew that putting financial pressure on Minerva at an early stage could put them out of business. Right?

"Answer: No, I don't recall that at all.

"Question: Sir, Exhibit 1 is an e-mail from you; right?

"Answer: Yes.

"Question: And you began, 'While you don't know me yet, I have past experience in a startup company.'

"Do you see that?

"Answer: Yes.

"Question: And then you write, 'The best thing we can do is not let them get a footing in any market.'

"Do you see that?

"Answer: I do.

"Question: 'This will put tremendous financial pressure on their entire organization and we will step them in their tracks.'

"Do you see that?

"Answer: Yes.

"Question: And so this is what we were talking about before, that your goal was to put financial pressure [1873] on Minerva. Right?

"Answer: Sure.

"Question: To stop them in their tracks?

"Answer: Right.

"Question: And put them out of business?

"Answer: That's what I said here, right. It's in an e-mail.

"Question: And that was your goal. Right?

"Answer: No. Actually, I don't think it was what the goal was. I don't think there's any reasonable person would think that we were going to keep them from having any cases. I think what I was trying to do is motivate and really get the team focused and energized and excited about selling our story. Because if you look at the rest of the e-mail from all of the folks involved from the beginning, whether it was Dan or Brian, up to Whit, it was really about this message, which was the Hologic story and our NovaSure message.

"So I wouldn't characterize my comments after having been there for a week as clear direction that they shouldn't let a case happen.

"Question: Now, you also had discussions with Ms. Parachek about implementing a 'scorched earth,' strategy to beat Minerva. Right?

"Answer: Yeah. I don't recall that.

[1874] "Question: I'm handing you what I've marked as Exhibit 2, which is an October 2nd, 2015, e-mail from you to Ms. Parachek, Bill Fruhan and Edward Evantash.

"Answer: Okay. What's the question?

"Question: Do you see Exhibit 2 starts with an e-mail from yourself --

"Answer: Right.

"Question: -- where you write, where are we with the Minerva defense program we discussed last week at dinner?

"Answer: Yes.

"Question: And Ms. Parachek responds, Tom, sorry for the delay. I planned to respond to this during our one-on-one, but we did not get to it. We have an outline of aggressive ideas for a scorched earth strategy that I will forward.

"Do you see that?

"Answer: Yes.

"Question: And do you recall what that scorched earth strategy was?

"Answer: So the way I read it here with what Whitney outlines is it has to do with leveraging our Med Affairs Group and making sure that we were putting together a co-op marketing program to drive partnership and growth. That's the way I read this.

* * * *

[1877] (End of videotaped deposition.)

* * * *

[1948] MR. BISH: Your Honor, Minerva offers the video deposition testimony from Ms. Shacey Petrovic, who is the former vice president and general manager for Hologic's gynecological surgical division in the 2013 time frame.

(The videotaped deposition of Shacey Petrovic was played as follows.)

* * * *

[1951] "Question: I've handed you what's been marked now Exhibit 16, HOL-MIN_10 -- excuse me, 016205 on its face. And can you confirm this is the attachment to the e-mail from Mr. Williamson of Exhibit 15?

"Answer: Yes.

"Question: And it's titled strategy planning meeting key themes and takeaways. Correct?

"Answer: Yes.

"Question: And at this point in time, which his e-mail again is dated June 17, 2011, Minerva has not appeared on the market. Correct?

"Answer: Correct.

"Question: You don't recall any concern at all about IP expiring with respect to the NovaSure?

"Answer: I really don't.

"Question: And here Mr. Williamson is exhorting the team to accelerate our time to market of that smaller diameter NovaSure device?

"Answer: Yes.

"Question: When -- at the very bottom bullet point, it says, 'Our Gen 4 team must focus their efforts on laying minefields around our product to: A, prevent more entrants into this field; B, protect our current portfolio.'

[1952] "Do you see that?

"Answer: Yes.

"Question: What did Mr. Williamson mean by laying minefields around our product?

"Answer: I understand that to mean additional patent protection.

"Question: Okay. So was there any discussion of filing for additional patents, for example?

"Answer: I don't recall that specifically.

"Question: Okay. What is it -- as specific as you can recall, what is he referring to exactly with respect to 'laying minefields around our product?'

"Answer: My understanding is he's asking the R&D team to continue to create valuable IP in order to protect new entrants from entering the market.

"Question: What you recall. But there was a concern to prevent more entrants into this field, being global endometrial ablation. Correct?

"Answer: Yes.

"Question: Okay.

"Answer: I don't believe that was the only feature associated with the next generation NovaSure device.

"Question: Okay. But it was a feature?

"Answer: Yes.

* * * *

[2319] IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CIVIL ACTION NO. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs and Counterdefendants,

vs.

MINERVA SURGICAL, INC.,
Defendant and Counterclaimant.

Wilmington, Delaware
Thursday, July 26, 2018
9:00 o'clock, a.m.

VOLUME 9

BEFORE: HONORABLE JOSEPH J. BATAILLON, U.S.D.C.J., and a jury

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* * * *

[2419] MR. WOLF:

* * * *

[2425] Remember Mr. Truckai said, nothing in 2009 to 2010 was confidential. And nothing that becomes generally public. We saw the AAGL. All the product stuff was already out in the public. That's the AAGL.

* * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 15-1031-JFB-SRF

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

v.

MINERVA SURGICAL, INC.,
Defendant.

JUDGMENT FOLLOWING JURY VERDICT

This action came before the Court for a trial by jury beginning on July 16, 2018. The jury rendered its verdict on July 27, 2018. The verdict was accompanied by the verdict form (D.I. 498 and 499), a copy of which is attached hereto.

On June 28, 2018, the Court issued an Order, *inter alia*, granting Plaintiffs' motion for a summary judgment of no invalidity, Plaintiff's motion for a summary judgment of infringement, and Plaintiffs motion for a summary judgment with respect to assignor estoppel. D.I. 408.

IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered on the July 27, 2018 verdict as set forth in the attached verdict form and on the June 28, 2018 Order (D.I. 408).

IT IS FURTHER NOTED that this Judgment Following Jury Verdict is subject to revision pursuant to any rulings on post-trial motions.

IT IS SO ORDERED AND ADJUDGED.

August 13, 2018

/s/ Joseph F. Bataillon
SENIOR UNITED STATES
DISTRICT JUDGE

Trials@uspto.gov Paper 8

Tel: 571-272-7822 Entered: September 12, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

Case IPR2016-00680
Patent 9,095,348 B2

Before WILLIAM V. SAINDON, RICHARD E. RICE, and NEIL T. POWELL, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Minerva Surgical, Inc. ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1–15 ("the challenged claims") of U.S. Patent

No. 9,095,348 B2 (Ex. 1001, "the '348 Patent"). Petitioner supported the Petition with a Declaration from John Anthony Pearce, Ph.D. (Ex. 1002). Hologic, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.").

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we do not institute *inter partes* review.

B. Related Proceedings

We are informed that Petitioner is named as a defendant in a federal district court case involving the '348 Patent (Case No. 1:15-cv-01031-SLR pending in the U.S. District Court for the District of Delaware). Pet. 14. We also are informed that Petitioner has filed a second Petition for *inter partes* review of the '348 Patent (IPR2016-00685). *Id.*

C. The '348 Patent

The '348 Patent, titled "Moisture Transport System for Contact Electrocoagulation," issued from an application filed August 8, 2013, and claims priority to May 8, 1998. Ex. 1001, at (54), (21), (22), (60), 1:6–13. The '348 Patent relates to an apparatus for ablating the interior linings of body organs such as the uterus. *Id.* at 1:19–21. Ablation of the interior lining of a body organ, the '348 Patent explains, "involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis."

Id. at 1:26–28. Ablation may be performed, for example, to treat chronic bleeding of the endometrial layer of the uterus. *Id.* at 1:28–30. The '348 Patent states that conventional methods of effecting ablation include "application of RF energy [i.e., radio frequency energy] to the tissue to be ablated." *Id.* at 1:31–35. Problems addressed by the '348 Patent include the need for a device that eliminates steam and liquid buildup at the ablation site and that allows control of the depth of ablation in the treated tissue. *Id.* at 1:48–2:30.

Figure 21 of the '348 Patent, which is reproduced below, illustrates ablation device 100:

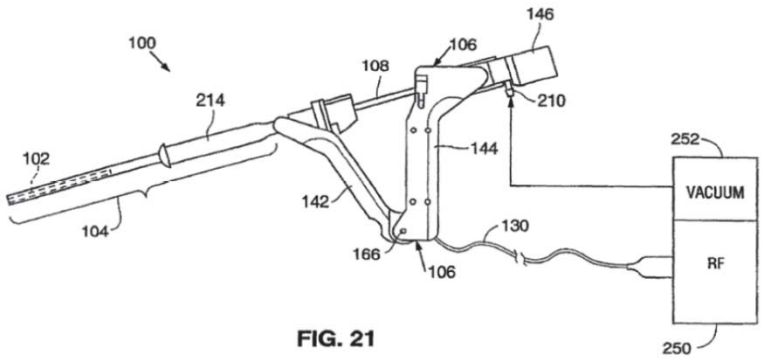


FIG. 21

Figure 21 is a side elevation view of ablation device 100 showing sheath 104, tubing 108, handle 106, and RF applicator head 102 slidably disposed within sheath 104. *Id.* at 11:59–62, 12:2–5. After insertion of the device into the uterine cavity, manipulation of handle 106 causes the applicator head to extend from the distal end of the sheath and to expand into contact with body tissue. *Id.* at 11:63–12:5. The ablation device can be used to measure the width of the uterus, and gauge 146 displays the measured width. *Id.* at 14:33–36. The measured width is entered into RF

generator system 250 and used to calculate the ablation power. *Id.* at 18:37–39. Vacuum source 252 is connected to inner hypotube 122 (discussed below) via suction port 210. *Id.* at 18:40–41.

As illustrated in Figure 23 of the '348 Patent, which is reproduced below, applicator head 102 extends from the distal end of tubing 108. *Id.* at 12:2–5.

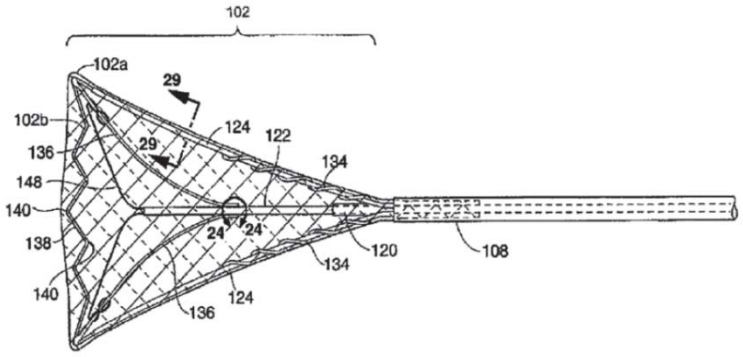


Figure 23 illustrates applicator head 102 in the expanded or deployed state.[1] *See id.* at Fig. 23. Applicator head 102 includes: external electrode array 102a, which is formed of a stretchable metallized fabric mesh; an internal deflecting mechanism 102b, which is used to expand and tension the electrode array for positioning into contact with uterine tissue; and non-conductive suturing threads 148, which extend from hypotube 122 for use in measuring the width of the uterus. *Id.* at 12:5–12, 14:33–39.

The deployment structure for deflecting mechanism 102b includes external hypotube 120, which extends from tubing 108, and internal hypotube 122, which is slidably and co-axially disposed within hypotube 120.

---

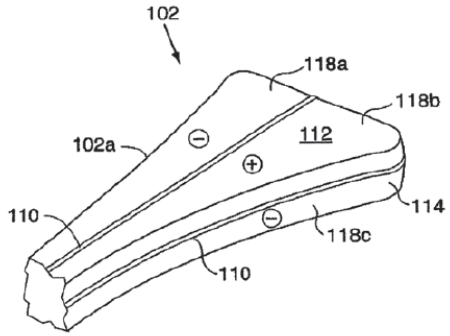
[1] The '348 Patent states that, for clarity, sheath 104 is not shown in Figure 23. *Id.* at 12:2–3.

Id. at 13:8–12. Outer flexures 124 extend laterally and longitudinally from tubing 108 on opposite sides of external hypotube 120. *Id.* at 13:12–13. Internal flexures 136 extend laterally and longitudinally from the exterior surface of internal hypotube 122. *Id.* at 13:56–58. Each internal flexure 136 is connected at its distal end to one of the outer flexures 124, and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. *Id.* at 13:58–61. As described in the '348 Patent,

> during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

Id. at 14:25–31.

Deflecting mechanism 102b and its deployment structure are enclosed within electrode array 102a. *Id.* at 13:8–9. Figure 25A of the '348 Patent is a perspective view of electrode array 102a in the deployed or expanded state. *Id.* at 3:52–53, 12:53–55. Figure 25A is reproduced below.



As shown in Figure 25A, insulating regions 110 are formed on the applicator head to divide the mesh into electrodes 118a–118d. *Id.* at 12:59–13:7. As power is supplied to the electrodes, the tissue is heated, releasing moisture. *Id.* at 18:44–47. Moisture is withdrawn from the uterine cavity through internal hypotube 122, which is connected to vacuum source 252. *Id.* at 18:47–49. Apertures formed in outer flexures 124 facilitate moisture withdrawal by preventing trapping of moisture between the flexures and the lateral walls of the uterus. *Id.* at 18:49–52.

Handle 106 comprises distal and proximal grip sections 142, 144, which are pivotally attached to one another at a pivot pin. *Id.* at 16:13–16, Figs. 21– 22. Proximal grip section 144 is coupled to hypotube 122 via yoke 168, overload spring 170, and spring stop 172. *Id.* at 16:17–19, 17:38–40, Figs. 34, 37A, 37B. Distal grip section 142 is coupled to external hypotube 120 via male and female couplers 174, 176. *Id.* at 16:20–22, Figs. 32A, 32B, 34. Figure 34 of the '348 Patent is reproduced below.

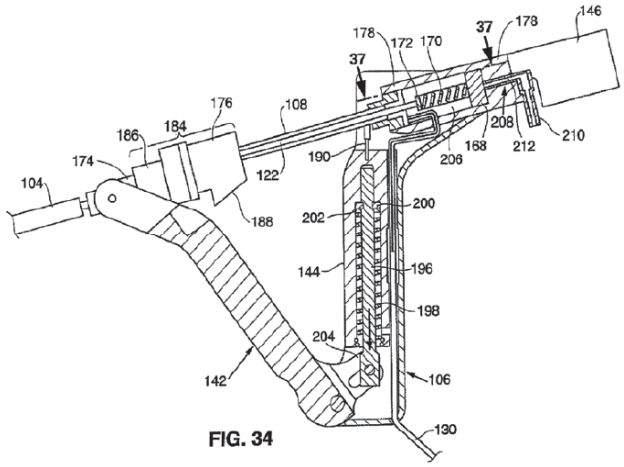


FIG. 34

Figure 34 is a side elevation view of handle 106 as depicted in Figure 21 (reproduced above). *Id.* at 4:19–21.

As the distal and proximal grips are moved towards one another, sheath 104 is withdrawn from array 102a until female coupler 176 contacts and bears against frame member 178. *Id.* at 17:54–59, Fig. 37A, 37B. "Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120." *Id.* at 17:59–61. "An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122." *Id.* at 17:61–63, Figs. 37A, 37B. "The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array." *Id.* at 17:63–66.

D. Illustrative Claims

Claims 1 and 11 are independent. Claims 2–10 and 12 depend, directly or indirectly, from claim 1; claims 13–15 depend directly from claim 11. Claims 1 and 11

are illustrative of the claimed subject matter, and are reproduced below:

> 1. A device for treating a uterus comprising:
>
> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
>
> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured

so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

Id. at 19:9–42.

11. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer

sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

Id. at 20:17–47.

E. The Asserted References

Petitioner relies upon the following references (Pet. 14–15):

Reference	**Patent No./ Pub. No.**	**Date**	**Exhibit No.**
Yoon	US 5,514,091	May 7, 1996	Ex. 1007
Nady-Mohamed	US 5,353,784	Oct. 11, 1994	Ex. 1009
Ortiz	US 5,358,496	Oct. 25, 1994	Ex. 1006
Jing	CN 1060594A	Published Apr. 29, 1992	Exs. 1010, 1011 (translation)
Lichtman	US 5,620,459	Apr. 15, 1997	Ex. 1008

F. The Asserted Grounds

Petitioner challenges claims 1–15 of the '348 Patent on the following grounds (Pet. 14–15):

References	Basis	Claim(s) Challenged
Yoon, Nady-Mohamed, Ortiz, and Jing	§ 103(a)	1–7, 10–13, and 15
Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman	§ 103(a)	8, 9, and 14

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Level of Skill in the Art

Dr. Pearce testifies that a person of ordinary skill in the art

> would include someone who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices.

Ex. 1002 ¶ 47. Patent Owner does not provide evidence or argument on the level of ordinary skill. Prelim. Resp. 11 n.3. We adopt Dr. Pearce's definition for purposes of this Decision.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a

claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes express constructions for two claim terms, "frame" and "flexure." Pet. 15–17. Patent Owner does not propose an express construction for any claim term. Prelim. Resp. 9–10,

1. "frame"

Claim 1 recites "a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a *frame*" (emphasis added). Petitioner proposes to construe the term "frame" "to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve)." Pet. 16.

We have considered Petitioner's proposed claim construction, but determine that the term "frame" does not require explicit construction for purposes of our Decision. We note, however, that this term was construed in a related case (IPR2016-00685).

2. flexures

Claim 1 recites "a deflecting mechanism including *flexures* disposed within the applicator head" (emphasis added). Petitioner argues that the term "flexure" "should be construed to include a component designed to be bent or curved." *Id.* at 17. Petitioner asserts that its proposed claim construction is consistent with the use of "flexure" in the Specification and the term's ordinary meaning. *Id.* at 16–17 (citing Ex. 1001, 13:65–67, 13:56–14:31, Figs. 23, 30; Ex. 1002 ¶¶ 54–56; Ex. 1013, 3).

We do not agree with Petitioner's proposed construction because it is not consistent with the Specification's description of flexures 124, 136 as strips that are capable of being bent or curved. *See*, *e.g.*, Ex. 1001, 4:1–9, 13:8–14:31, Figs. 23, 28–30. Figures 23 and 28, for example, depict flexures 124 as strips that have been bent or curved as the result of relative motion between hypotubes 120 and 122. *Id.* at 13:8–15, 14:29–30, Figs. 23, 28. Indeed, Petitioner's declarant, Dr. Pearce, testifies that "a person of skill in the art would understand the term 'flexure' to refer to a component capable of being bent or curved." Ex. 1002 ¶ 56.

On this record, we determine that the broadest reasonable interpretation consistent with the Specification of "flexures" is strips that are capable of being bent or curved. We note that a distinction with Petitioner's proposed construction is that "designed to be bent," for example, could mean a structure that has been bent but is no longer bendable or a structure that is bendable. "Capable of being bent," on the other hand, means that the structure is further bendable.

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art ("POSA") to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In this case, Petitioner challenges claims 1–15 as unpatentable for obviousness. Pet. 14–15. Specifically, Petitioner contends that claims 1–7, 10–13, and 15 would have been obvious over Yoon, Nady-Mohamed,

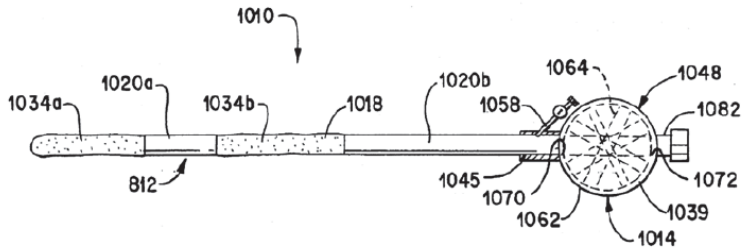
Ortiz, and Jing and claims 8, 9, and 14 would have been obvious over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman. *Id.* For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

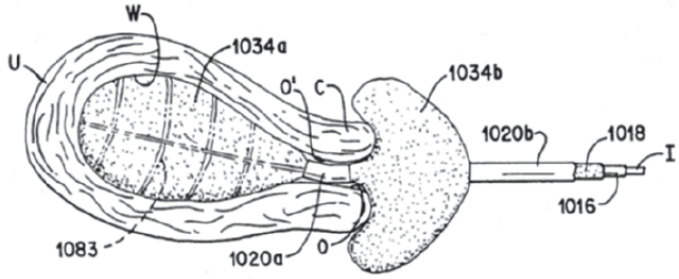
1. Overview of Asserted References

a. Yoon

Yoon discloses several distinct embodiments, including multifunctional instrument 410, which can be used for performing various diverse operative procedures, including uterine ablation. Ex. 1007, 20:9–38. Instrument 410 includes inner member 416 and middle member 418. *Id.* at 20:19. Middle member 418 is made as a collapsible bag, balloon, or membrane. *Id.* at 19:67–20:5. The middle member defines expandable portions 434a and 434b, which have "preformed predetermined" shapes. *Id.* at 19:55–59. Expandable portions 434 are introduced through an opening in the body in a collapsed state, and fluid is supplied between middle member 418 and inner member 416 to move the expandable portions from the collapsed state to an expanded state in which they form enlargements or protrusions having configurations corresponding to the preformed predetermined shapes. *Id.* at 20:9–38, Fig. 13. Middle member 418 may include electrically conductive material, such as an electrically conducting spine, for use in performing uterine ablation. *Id.* at 20:34–38

Yoon also discloses multifunctional instrument 1110. *Id.* at 24:63–29:7, Figs. 23–27. Figures 23 and 24 are reproduced below.





The first figure above is Figure 23, which shows a side view of instrument 1010 with expandable portions 1034 in the unexpanded state, and the second above figure is Figure 24, which shows expandable portions 1034 in the expanded position. *Id.* at 5:33–38, 25:20–31. "Multifunctional instrument 1010 is particularly advantageous for performing endometrial ablation to treat, for example, dysfunctional uterine bleeding in that an electrically conductive spine 1083, shown in dotted lines in FIG. 24, can be disposed within or on middle member 1018 for contacting anatomical tissue." *Id.* at 26:26–32.

Figures 25–27 illustrate a further modification of instrument 1010. *Id.* at 26:41–29:7. As modified, instrument 1010 includes inner member 1116, middle member 1118, and collar 1120. *Id.* at 26:43–48. Middle member 1118 includes a transparent stretchable or elastic membrane or a non-elastic or rigid preformed membrane having distal end wall 1126, which closes

off or seals the lumen of the middle member; inner member 1116 carries expandable spine 1183 for mechanically shaping or expanding middle member 1118. *Id.* at 26:43–48, 27:40–44. Spine 1183 includes plurality of legs 1192 pivotally or hingedly attached to inner member 1116 at pivots, joints, or hinges. *Id.* at 26:54–56. The legs can be attached pivotally to the inner member 1116 at various locations in accordance with the configuration desired for expandable portion 1134 in the expanded position. *Id.* at 26:56–61. Figure 26 of Yoon is reproduced below.

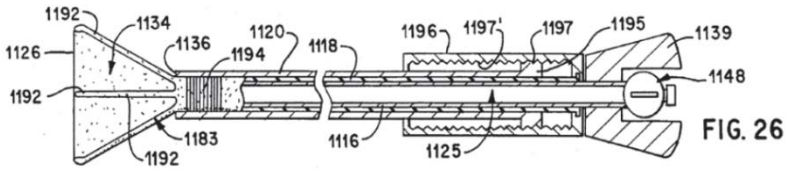


FIG. 26

As shown in Figure 26, spine 1183 is biased to, or normally disposed in, an expanded position wherein legs 1192 are disposed angularly outwardly of inner member 1116. *Id.* at 26:61–63. The legs are equally spaced about a longitudinal axis of the instrument. *Id.* at 26:56–61. Yoon discloses that:

> As shown in FIG. 26, operating cylinder 1196 is rotated until forward edge 1136 of collar 1120 is disposed proximally of expandable portion 1134 causing spine 1183 to move automatically to the expanded position with legs 1192 disposed in a direction angularly outwardly of the instrument longitudinal axis as shown in FIG. 26.

Id. at 28:41–46. Yoon also discloses that:

> Movement of spine 1183 to the expanded position causes movement of expandable portion 1134 to the expanded position forming an enlargement or protrusion between end wall 1126 and collar

> forward edge 1136. *If desired, fluid can be supplied to expandable portion 1134* via valve assembly 1148 and the lumen 1125 of inner member 1116 to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position. In the expanded position, the expandable portion 1134 can be used to manipulate tissue or organ structure in the anatomical cavity for various medical procedures.

Id. at 28:46–57 (emphasis added).

b. Nady-Mohamed

Nady-Mohamed relates to barrier-forming or shielding means insertable into a cavity within the body through a small incision. Ex. 1009, 1:6–10. A disclosed embodiment includes cylindrical tube 10, plunger 11, and flexible arms 13, 14, which are preformed to their operative extended shapes. *Id.* at 3:45–4:6. "A membrane 20 is disposed between the arms 13 and 14, and is fixed to each arm along the lengths of its outer edges." *Id.* at 3:67–4:1. Nady-Mohamed discloses:

> In the retracted position, as illustrated in FIG. 1, the membrane 20 is folded or otherwise compressed for storage between the arms. In the extended position, as illustrated in FIGS. 2 and 3, the previously deformed arms 13 and 14 attain their natural shape, and membrane 20 is thereby spread to occupy the space between them.

Id. at 4:1–6. Figure 3 of Nady-Mohamed is reproduced below.

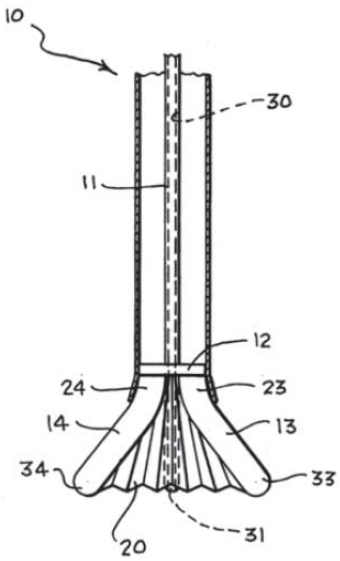
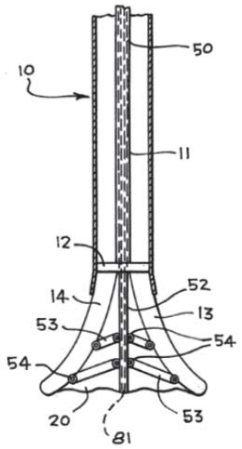


Figure 3 is a cross-section view of the barrier-forming apparatus showing plunger 11 and arms 13, 14 in an extended position, with membrane 20 spread between them. *Id.* at 3:17–19. Plunger 11 is slidably disposed within tube 10, "and the arms and membrane are expelled from the distal end of the tube or withdrawn into the tube by sliding the plunger in the desired direction." *Id.* at 4:53–56. In use, for example, "the distal end of the tube is placed in the vicinity of the organ or tissue of interest, and the membrane and arms are extended from within the tube, thereby forming a solid barrier for shielding or retraction of the organ." *Id.* at 5:52–56.

Figure 6 of Nady-Mohamed, reproduced below, depicts a structure for adding rigidity to arms 13, 14 in their extended position. *Id.* at 5:12–14.

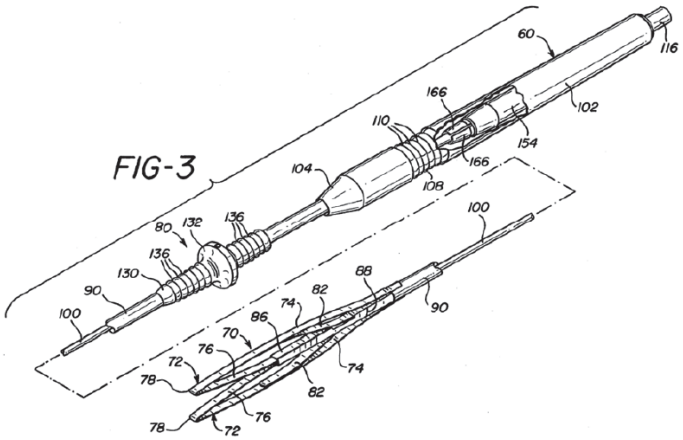


As shown in Figure 6, plunger 11 terminates at disc 12, which has a longitudinal bore within which rod 50 is slidably disposed. *Id.* at 5:14–17. "The rod near its distal end 52 is provided with a plurality of *rigid* ribs 53 which are pivotally joined to the outer surface of the rod at pivotal joints 54." *Id.* at 5:18–21 (emphasis added). "The ribs extend laterally from the rod and are pivotally joined at their opposite ends to the arms 13 and 14, such that, when the arms are urged by the plunger to their extended position, the rod is drawn forward with the arms, and the ribs are spread by the expansion of the arms." *Id.* at 5:21–26. A locking feature prevents movement of the rod toward the proximal end of the apparatus. *Id.* at 5:32–39. "The locking feature is of *critical importance* in applications in which it is necessary for the arms to resist a collapsing force." *Id.* at 5:39–43 (emphasis added).

c. Ortiz

Ortiz relates to an endoscopic tissue manipulator that can be inserted through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity. Ex. 1006, 1:10–12. A preferred embodiment

includes a proximal handle assembly and a distal expandable platform 70. *Id.* at 4:37–39. Figure 3 of Ortiz is reproduced below:



As shown in Figure 3, platform 70 consists of a plurality of flexible, interconnected strips adapted to expand laterally outward to form a pair of fingers 72. *Id.* at 4:52–55. Each of fingers 72 comprises outer strip 74 and inner strip 76. *Id.* at 4:55–58. Outer strip 74 is attached to the distal end of actuator tube 90, and inner strip 76 is attached to the distal end of shaft or push rod 100 inside of actuator tube 90. *Id.* at 4:59–63. "[W]hen actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration." *Id.* at 5:28–31. "The outer strips 74 are pulled in the proximal direction by the actuator tube 90 and the guide tube 86 is moved proximally along the inner strips 76 by the struts 82." *Id.* at 5:32–34. Figure 7 of Ortiz is reproduced below.

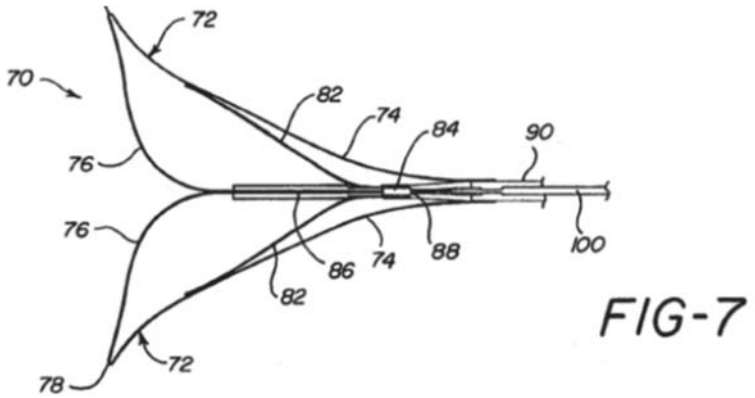


FIG-7

Figure 7 depicts a longitudinal cross section illustrating platform 70 in a tulip-shaped configuration. *Id.* at 3:29–30, 4:10–11. As shown in Figure 7, each of fingers 72 comprises flexible strut 82, having its distal end secured to outer strip 74 and its proximal end attached to connector sleeve 84, which is slidably mounted on inner strip 76. *Id.* at 4:63–5:1. Connector sleeve 84 is located within guide tube 86, which is slidably received in the distal end of actuator tube 90. *Id.* at 5:1–4. Struts 82 provide for shape control of platform 70 in its expanded configuration. *Id.* at 6:1–2. "The expanded platform 70 has a generally planar configuration which provides two flat tissue manipulating surfaces on its opposite sides." *Id.* at 8:36–39.

d. Jing

Jing relates to a computer-controlled apparatus for measuring and displaying data of the morphology of a woman's uterine cavity. Ex. 1011, 3:5–7, 20–23, 4:25–30.[2] "An object of the present invention is to provide a computer-controlled measurement apparatus for measuring and displaying data of the morphology of

[2] We cite to the certified translation of Jing (Ex. 1011).

the uterine cavity, thereby increasing the success rate of the IUD technique and facilitating the modification of IUDs." *Id.* at 3:20–23. Figure 2 of Jing is reproduced below.

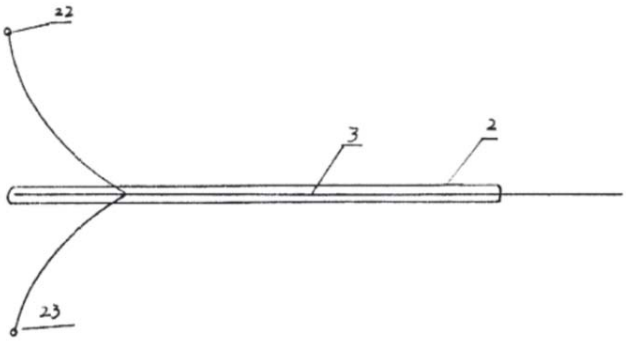


Figure 2 illustrates measuring rod 3 and dovetail-type contacts 22, 23. *Id.* at 5:9–13. Jing discloses:

> When a transverse dimension of the uterine cavity is to be measured, the measurement push button may be pushed by hand, such that two dovetail-type contacts (22, 23) of the transverse dimension measuring rod protrude from through-holes (10) at two sides of the measurement sleeve and expend [sic] to the transverse dimension being measured.

Id.

2. Petitioner's Contentions with Respect to Claims 1 and 11

With respect to the requirement of claims 1 and 11 for an elongate member comprising an inner sleeve slidably and coaxially disposed within an outer sleeve, Petitioner relies on Yoon's instrument 1110 as depicted in Figure 25. Pet. 22–23. Petitioner also argues: "To the extent that Yoon does not expressly describe an inner sleeve slidably disposed within the

outer sleeve as recited in the claim, these aspects of the limitation are fully disclosed by Nady-Mohamed." *Id.* at 23 (citing Ex. 1002 ¶ 182). Relying on the embodiment depicted in Nady-Mohamed's Figure 6, Petitioner asserts that Nady-Mohamed's rod 50 (i.e., the inner sleeve) is slidably disposed within Nady-Mohamed's plunger 11 (i.e., the outer sleeve). *Id.* (citing Ex. 1009, 5:14–18, Fig. 6; Ex. 1002 ¶ 183). As reasons for combining the teachings of Yoon and Nady-Mohammed, Petitioner asserts:

> One of ordinary skill in the art would have incorporated an expansion mechanism as in Nady-Mohamed into an ablation device as disclosed by Yoon, because Yoon teaches that different expansion mechanism designs can be used and Nady-Mohamed's mechanical expansion elements are specifically designed for engaging the uterine walls. Ex. 1002 ¶¶ 169-171, 184. In addition, as Dr. Pearce also explains, use of the mechanical expansion elements taught by Nady-Mohamed, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid expansion media disclosed in Yoon because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination.

Id. at 24 (citing Ex. 1002 ¶¶ 173, 184).

With respect to the "deflecting mechanism" limitation requiring "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve," Petitioner relies on combining features of Yoon's instrument 1010 as depicted in Figures 25–27 with the embodiment depicted in Nady-Mohamed's Figure 6. *Id.* at 31–32. Petitioner asserts that Nady-Mohamed's flexible arms

13, 14 correspond to the "external flexures" limitation and that Nady-Mohamed's rigid ribs 53 correspond to the "internal flexures" limitation. *Id.* Petitioner argues that a skilled artisan would have improved Yoon's ablation device by incorporating Nady-Mohamed's mechanical expansion design:

> Moreover, a skilled artisan would have recognized that an endometrial ablation device as in Yoon would benefit from improved contact between the expandable applicator head and the uterine wall. [Ex. 1002 ¶ 171.] The mechanical expansion design disclosed in Yoon utilizes straight, rigid "legs" in its "expandable spine." Ex. 1007 at 26:53–56, FIGS. 25–27 (elements 1192). Nady-Mohamed discloses a similar triangular shape for its expandable head, but teaches the use of flexible supports for the structure, teaching that its flexible arms are beneficial for "firmly engag[ing] the walls of the lumen of the uterus without risk of tearing or other damage to the tissue." *See* Ex. 1009 at 4:30-33. It would have been apparent to the skilled artisan that this arrangement would be beneficial for maintaining stable contact between the applicator head and uterine walls during endometrial ablation. Ex. 1002 ¶ 171.

Id. at 50–51.

Petitioner additionally contends that, "[t]o the extent the ribs 53 pivotally coupled to the sleeve 81 and flexures 13, 14 themselves do not satisfy as flexures, it would have been obvious to use bendable components such as those described in Ortiz." *Id.* at 32 (citing Ex. 1002 ¶ 206). Petitioner asserts that "Ortiz discloses first and second outer flexures, each referred to as 'outer strip 74,' and first and second inner

flexures, each referred to as 'flexible strut 82.'" *Id.* (citing Ex. 1002 ¶ 206). As reasons to combine Yoon, Nady-Mohamed, and Ortiz, Petitioner contends:

> Dr. Pearce explains that it would have been obvious to a person of ordinary skill in the art to implement flexible reinforcing ribs capable of achieving some degree of curvature, since this would merely be a simple substitution of one known element for another. [Ex. 1002 ¶ 207.] Substituting pivoting ribs 53 with fixed flexible members would still provide structural definition for the expandable device while at the same time providing flexibility and ability to conform to the walls of the uterus. *Id.*
>
> Additionally, a person of ordinary skill would reasonably have incorporated a flexible design as in Ortiz's expandable platform, including its bendable inner flexures, into an ablation device such as disclosed by Yoon. *Id.* ¶¶ 172–173. Utilizing a "plurality of flexible, interconnected strips" and "flexible struts" such as taught by Ortiz would further improve the ability of the device to conform to the shape of the uterus and accommodate different morphologies while also providing sufficient support to maintain an appropriate shape for uterine treatment. Ex. 1006 at 4:34–42, 52–55; Ex. 1002 ¶¶ 172–173.

Id. at 33; *see also id.* at 51–52 (advancing similar arguments).

With respect to the requirement of claims 1 and 11 for "an indicator mechanism coupled to the inner sleeve . . . configured to indicate a dimension of the uterus," Petitioner relies on Jing's device for measuring a transverse dimension of the uterine

cavity. Pet. 35–37. Petitioner contends that a skilled person would have incorporated Jing's measurement apparatus into the ablation device taught by Yoon, Nady-Mohamed, and Ortiz "in order to provide dimension information that would assist a physician in accounting for patient-to-patient variations in uterine morphology, and thereby increase the safety and efficacy of the ablation treatment." *Id.* at 37, 52–54 (citing Ex. 1002 ¶ 176). Petitioner further argues that "it would have been common sense to the skilled artisan at the time that information regarding internal morphology would be useful when operating a surgical device within a confined space such as the uterus without direct observation." *Id.* at 54 (citing Ex. 1002 ¶ 176).

3. Patent Owner's Responsive Contentions

In response, Patent Owner argues, *inter alia*, that Petitioner has not explained sufficiently why a person of ordinary skill in the art would have combined the prior art teachings to arrive at the challenged claims as a whole. *See* Prelim. Resp. 14–15, 39, 60. Patent Owner argues, for example, that "Petitioner relies on a combination of three prior art references for the 'deflecting mechanism' limitations of claims 1 and 11," but "fails to provide a rationale (or provides only insufficient conclusory assertions) for combining these references." *Id.* at 29.

Patent Owner also asserts that Petitioner has failed to show why or how incorporating Nady-Mohamed's deflecting mechanism into Yoon's embodiment 1110 would have improved contact between Yoon's expandable applicator head and the uterine wall as Petitioner contends. *Id.* at 31–32. Patent Owner further argues that "the straight, rigid ribs 53 of Nady-Mohamed are not 'flexures.'" *Id.* at 31.

Patent Owner additionally contests Petitioner's rationale "for combining Ortiz's struts 82 with Nady-Mohamed's deflecting mechanism." *Id.* at 32–33. Patent Owner argues that, even if the references are, as Petitioner contends, in the same field of endeavor, that fact alone is insufficient to show a rationale for combining the references. *Id.* at 33. Patent Owner characterizes Petitioner's further argument that "the 'flexible construction' of Ortiz's struts 82 would 'improve the ability of [Nady-Mohamed's] device to accommodate different uterine morphologies'" as conclusory and lacking "any factual support or reasoning as to how Ortiz's struts 82 could improve Nady-Mohamed's ability to accommodate different uterine morphologies if used as inner flexures." *Id.* (quoting Pet. 51).

Patent Owner asserts that "Nady-Mohamed's arms 13 and 14 are described as 'preformed to their operative extended shape' and 'attain their natural shape' in the extended position—i.e., Nady-Mohamed's arms 13 and 14 are intended to expand to their predetermined shape regardless of whether Ortiz's struts 82 are used." *Id.* at 33–34 (quoting Ex. 1009, 3:55–58, 4:3–6). Patent Owner additionally asserts that "Petitioner also has not provided any evidence that a person of ordinary skill would have recognized the alleged benefit of the Ortiz struts in the context of the claimed invention (i.e., to accommodate different uterine morphologies) without hindsight." *Id.* at 34.

With respect to "an indicator mechanism operably coupled to the inner sleeve . . . configured to indicate a dimension of the uterus," Patent Owner asserts that Jing's transverse-dimension-measurement device is a stand-alone-apparatus with dovetail-type contacts

that must extend across the full width of the uterus. *Id.* at 39–41 (Ex. 1011, 5:9–13). As such, Patent Owner argues, Jing is "inapposite to the devices described in Yoon, Nady-Mohamed, and Ortiz," and would not satisfy the "operably coupled to the inner sleeve" aspect of the claim limitation if coupled to Nady-Mohamed's outer sleeve to measure the width of the uterine cavity. *Id.* Patent Owner further asserts that Petitioner fails to explain sufficiently why or how a person of ordinary skill in the art would have used Jing's apparatus in combination with Yoon's expandable member 1034. *Id.* at 59–60.

4. Analysis

An analysis under 35 U.S.C. § 103(a) requires more than "mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Upon consideration of the Petition and the Preliminary Response, we agree with, and adopt, Patent Owner's argument, as summarized above, that the reasons advanced by Petitioner for combining elements of Yoon, Nady-Mohamed, Ortiz, and Jing to make the claimed invention are conclusory and insufficient. We provide additional analysis below.

Petitioner primarily relies on Nady-Mohamed for the inner-sleeve-slidably-disposed-within-an-outer-sleeve requirement.[3] In reference to the embodiment

[3] Petitioner also appears to contend that Yoon's instrument 1110 as depicted in Yoon's Figures 25–27 teaches an inner sleeve slidably disposed within an outer sleeve. *See* Pet. 22–23. Petitioner, however, does not identify the elements of Yoon's instrument 1110 that allegedly satisfy the claim requirements.

depicted in Nady-Mohamed's Figure 6, Petitioner identifies rod 50 of Nady-Mohamed as corresponding to the "inner sleeve" and Nady-Mohamed's plunger 11 as corresponding to the "outer sleeve." Pet. 23–24 (citing Ex. 1009, 5:14–18, Fig. 6; Ex. 1002 ¶ 183). While the identified elements would satisfy the "inner sleeve" and "outer sleeve" requirements, we determine, as discussed below, that Petitioner's asserted reasons for modifying Yoon's instrument 1110 to incorporate these and other elements are insufficient to support a legal conclusion of obviousness. *See id.* at 24.

In Yoon's instrument 1110 as depicted in Figures 25–27, cylinder 1196 is rotated to retract collar 1120 relative to spine 1183, which, when uncovered, expands automatically to deploy expandable portion 1034 via legs 1192. Ex. 1007, 28:41–46, Figs. 25–27. In the expanded position, legs 1192 extend angularly outward, and expandable portion 1134 forms an enlargement or protrusion between end wall 1126 and collar forward edge 1136. *Id.* at 28:46–50. Fluid can be supplied to expandable portion 1134 to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position. *Id.* at 28:50–54.

Petitioner argues that Nady-Mohamed's mechanical expansion elements, including the slidable sleeves, are designed for engaging the uterine walls, but this argument does not explain sufficiently how the slidable sleeves contribute to this design, or why a skilled person would have substituted Yoon's rotatable

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Indeed, Petitioner's declarant, Dr. Pearce, testifies that "Yoon does not expressly describe an inner sleeve slidably disposed within the outer sleeve as recited in the claim." *See* Ex. 1002 ¶ 181.

cylinder/collar with Nady-Mohamed's slidable sleeves. *See* Pet. 24 (citing Ex. 1002 ¶¶ 173, 184). Dr. Pearce's testimony is similarly conclusory. For example, Dr. Pearce testifies:

> [U]se of the mechanical expansion elements taught by Nady-Mohamed, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid expansion media disclosed in Yoon because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination. Such a combination would result in a device where an inner sleeve slidably and coaxially disposed within an outer sleeve as taught by Nady-Mohamed would be used to deploy the expandable member of Yoon within the uterus.

Ex. 1002 ¶ 184. Dr. Pearce's testimony fails to explain sufficiently why using an inner sleeve slidably disposed within an outer sleeve would have "simplified" Yoon's rotatable cylinder/collar deployment mechanism. Dr. Pearce's testimony also fails to explain sufficiently why substituting Nady-Mohamed's slidable sleeves for Yoon's rotatable cylinder/collar would have obviated using fluid expansion media to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position (as disclosed in Yoon).

Petitioner also relies on Nady-Mohamed for "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve." Specifically, Petitioner contends that Nady-Mohamed's arms 13, 14 and ribs 53 correspond, respectively, to the required "external flexures" and "internal flexures." Pet. 31–32. We agree with Patent Owner, however, that ribs 53 as disclosed in Nady-

Mohamed are "rigid"; they are not flexible or bendable, and, thus, do not constitute "flexures" under a proper claim construction. *See supra* Section II.B.2; Prelim. Resp. 31.

Alternatively, Petitioner argues that Ortiz remedies the lack of "internal flexures" in Yoon and Nady-Mohamed. Pet. 32. Petitioner relies on Dr. Pearce's testimony that substituting Nady-Mohamed's rigid pivoting ribs 53 with "flexible reinforcing ribs capable of achieving some degree of curvature," such as flexible struts 82 of Ortiz, would have been obvious as "a simple substitution of one known element for another." Pet. 33 (citing Ex. 1002 ¶ 207).

We are not persuaded that substituting Nady-Mohamed's ribs 53 with Ortiz's struts 82 would have amounted to a simple substitution of one known element for another. The functions of the two elements are significantly different. The function of Nady-Mohamed's ribs 53 is to add rigidity to flexible arms 13, 14 in response to a collapsing force, while the function of Ortiz's struts 82 is to provide for shape control of outer strips 74 and platform 70 in response to an expanding force (pulling or pushing of outer strips 74 by retraction or advancement of actuator tube 90). *Compare* Ex. 1009, 5:12–43, *with* Ex. 1006, 5:28–6:6. The different known functions of ribs 53 (Nady-Mohammed) and struts 82 (Ortiz) are in keeping with the different expansion mechanisms that they complement. Flexible arms 13, 14 of Nady-Mohamed are preformed such that they spring naturally into their extended position when unrestrained (Ex. 1009, 3:55–4:6), while Ortiz's outer strips 74 do not expand unless pulled or pushed by retraction or advancement of actuator tube 90 (Ex. 1006, 5:28–67). We are not persuaded, therefore, that

Ortiz teaches or suggests flexible reinforcing ribs as Dr. Pearce asserts, or that a skilled person would have combined the teachings of Nady-Mohamed and Ortiz as Petitioner contends.

Petitioner, moreover, has not provided a sufficient rationale for combining the teachings of Jing with those of Yoon, Nady-Mohamed, and Ortiz. Petitioner's argument that dimension information provided by Jing's measurement device would assist a physician in accounting for patient-to-patient variations in uterine morphology does not explain sufficiently why a person of ordinary skill in the art would have incorporated Jing's measurement device into Yoon's ablation device, rather than simply use Jing's device separately to obtain the information. We are unpersuaded by Dr. Pearce's testimony that "it would have been *common sense* to the skilled artisan at the time that information regarding internal morphology would be useful when operating a surgical device within a confined space such as the uterus without direct observation." *See* Ex. 1002 ¶ 176 (emphasis added); *Arendi S.A.R.L. v. Apple Inc.*, Appeal No. 2015-2073, 2016 WL 4205964, at *5 (Fed. Cir. Aug. 10, 2016) (stating that "'common sense' . . . cannot be used as a wholesale substitute for reasoned analysis and evidentiary support"). Dr. Pearce's testimony does not contain sufficient reasoning or evidentiary support to explain why obtaining a transverse dimension of the uterus while concurrently operating Yoon's ablation device would have been useful.

For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to independent claims 1 and 11 as obvious over Yoon, Nady-Mohamed, Ortiz, and Jing. As Petitioner's arguments and evidence with respect

to dependent claims 2–10 and 12–15 do not remedy the deficiencies in the arguments and evidence with respect to the independent claims, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 2–10 and 12–15.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to: claims 1–7, 10–13, and 15 as obvious over Yoon, Nady-Mohamed, Ortiz, and Jing; and claims 8, 9, and 14 as over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's Petition for an *inter partes* review of claims 1–15 of the '348 Patent is *denied*, and no *inter partes* review will be instituted pursuant to 35 U.S.C. § 314 as to any claim of the '348 Patent on any of the grounds of unpatentability alleged by Petitioner in the Petition.

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Paper 8
Entered: September 12, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

Case IPR2016-00685
Patent 9,095,348 B2

Before WILLIAM V. SAINDON, RICHARD E. RICE, and NEIL T. POWELL, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Minerva Surgical, Inc. ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1–15 ("the challenged claims") of U.S. Patent No. 9,095,348 B2 (Ex. 1001, "the '348 Patent").

Petitioner supported the Petition with a Declaration from John Anthony Pearce, Ph.D. (Ex. 1002). Hologic, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.").

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we do not institute *inter partes* review.

B. Related Proceedings

We are informed that Petitioner is named as a defendant in a federal district court case involving the '348 Patent (Case No. 1:15-cv-01031-SLR pending in the U.S. District Court for the District of Delaware). Pet. 14. We also are informed that Petitioner has filed a second Petition for *inter partes* review of the '348 Patent (IPR2016-00680). *Id.*

C. The '348 Patent

The '348 Patent, titled "Moisture Transport System for Contact Electrocoagulation," issued from an application filed August 8, 2013, and claims priority to May 8, 1998. Ex. 1001, at (54), (21), (22), (60), 1:6–13. The '348 Patent relates to an apparatus for ablating the interior linings of body organs such as the uterus. *Id.* at 1:19–21. Ablation of the interior lining of a body organ, the '348 Patent explains, "involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis." *Id.* at 1:26–28. Ablation may be performed, for

example, to treat chronic bleeding of the endometrial layer of the uterus. *Id.* at 1:28–30. The '348 Patent states that conventional methods of effecting ablation include "application of RF energy [i.e., radio frequency energy] to the tissue to be ablated." *Id.* at 1:31–35. Problems addressed by the '348 Patent include the need for a device that eliminates steam and liquid buildup at the ablation site and that allows control of the depth of ablation in the treated tissue. *Id.* at 1:48–2:30.

Figure 21 of the '348 Patent, which is reproduced below, illustrates ablation device 100:

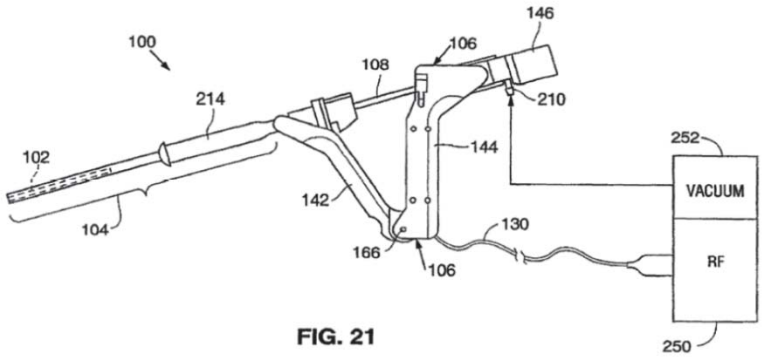


FIG. 21

Figure 21 is a side elevation view of ablation device 100 showing sheath 104, tubing 108, handle 106, and RF applicator head 102 slidably disposed within sheath 104. *Id.* at 11:59–62, 12:2–5. After insertion of the device into the uterine cavity, manipulation of handle 106 causes the applicator head to extend from the distal end of the sheath and to expand into contact with body tissue. *Id.* at 11:63–12:5. The ablation device can be used to measure the width of the uterus, and gauge 146 displays the measured width. *Id.* at 14:33–36. The measured width is entered into RF generator system 250 and used to calculate the

ablation power. *Id.* at 18:37–39. Vacuum source 252 is connected to inner hypotube 122 (discussed below) via suction port 210. *Id.* at 18:40–41.

As illustrated in Figure 23 of the '348 Patent, which is reproduced below, applicator head 102 extends from the distal end of tubing 108. *Id.* at 12:2–5.

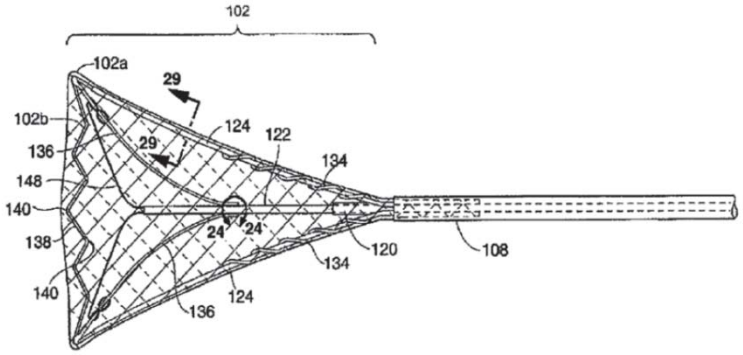


Figure 23 illustrates applicator head 102 in the expanded or deployed state.[1] *See id.* at Fig. 23. Applicator head 102 includes: external electrode array 102a, which is formed of a stretchable metallized fabric mesh; an internal deflecting mechanism 102b, which is used to expand and tension the electrode array for positioning into contact with uterine tissue; and non-conductive suturing threads 148, which extend from hypotube 122 for use in measuring the width of the uterus. *Id.* at 12:5–12, 14:33–39.

The deployment structure for deflecting mechanism 102b includes external hypotube 120, which extends from tubing 108, and internal hypotube 122, which is slidably and co-axially disposed within hypotube 120. *Id.* at 13:8–12. Outer flexures 124 extend laterally and

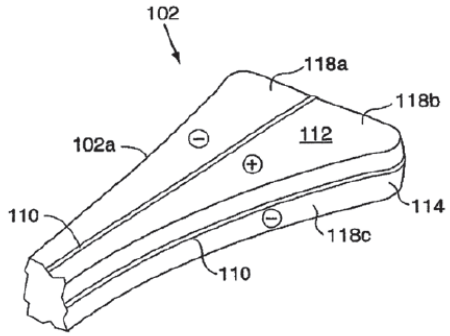
[1] The '348 Patent states that, for clarity, sheath 104 is not shown in Figure 23. *Id.* at 12:2–3.

longitudinally from tubing 108 on opposite sides of external hypotube 120. *Id.* at 13:12–13. Internal flexures 136 extend laterally and longitudinally from the exterior surface of internal hypotube 122. *Id.* at 13:56–58. Each internal flexure 136 is connected at its distal end to one of the outer flexures 124, and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. *Id.* at 13:58–61. As described in the '348 Patent,

> during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

Id. at 14:25–31.

Deflecting mechanism 102b and its deployment structure are enclosed within electrode array 102a. *Id.* at 13:8–9. Figure 25A of the '348 Patent is a perspective view of electrode array 102a in the deployed or expanded state. *Id.* at 3:52–53, 12:53–55. Figure 25A is reproduced below.



As shown in Figure 25A, insulating regions 110 are formed on the applicator head to divide the mesh into electrodes 118a–118d. *Id.* at 12:59–13:7. As power is supplied to the electrodes, the tissue is heated, releasing moisture. *Id.* at 18:44–47. Moisture is withdrawn from the uterine cavity through internal hypotube 122, which is connected to vacuum source 252. *Id.* at 18:47–49. Apertures formed in outer flexures 124 facilitate moisture withdrawal by preventing trapping of moisture between the flexures and the lateral walls of the uterus. *Id.* at 18:49–52.

Handle 106 comprises distal and proximal grip sections 142, 144, which are pivotally attached to one another at a pivot pin. *Id.* at 16:13–16, Figs. 21– 22. Proximal grip section 144 is coupled to hypotube 122 via yoke 168, overload spring 170, and spring stop 172. *Id.* at 16:17–19, 17:38–40, Figs. 34, 37A, 37B. Distal grip section 142 is coupled to external hypotube 120 via male and female couplers 174, 176. *Id.* at 16:20–22, Figs. 32A, 32B, 34. Figure 34 of the '348 Patent is reproduced below.

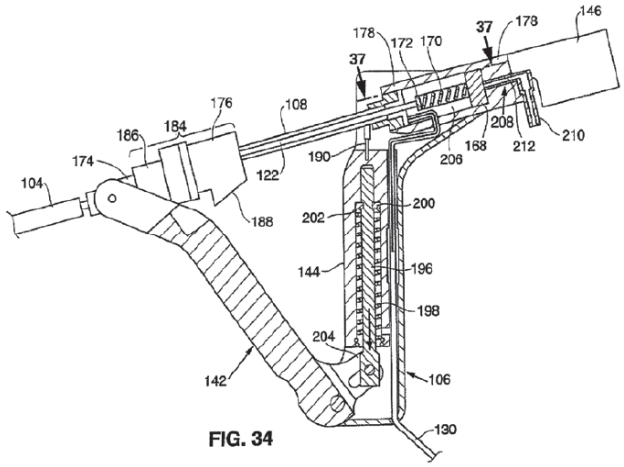


FIG. 34

Figure 34 is a side elevation view of handle 106 as depicted in Figure 21 (reproduced above). *Id.* at 4:19–21.

As the distal and proximal grips are moved towards one another, sheath 104 is withdrawn from array 102a until female coupler 176 contacts and bears against frame member 178. *Id.* at 17:54–59, Fig. 37A, 37B. "Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120." *Id.* at 17:59–61. "An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122." *Id.* at 17:61–63, Figs. 37A, 37B. "The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array." *Id.* at 17:63–66.

D. Illustrative Claims

Claims 1 and 11 are independent. Claims 2–10 and 12 depend, directly or indirectly, from claim 1; claims 13–15 depend directly from claim 11. Claims 1 and 11

are illustrative of the claimed subject matter, and are reproduced below:

> 1. A device for treating a uterus comprising:
>
> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
>
> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured

so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

Id. at 19:9–42.

11. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer

sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

Id. at 20:17–47.

E. The Asserted References

Petitioner relies upon the following references (Pet. 14):

Reference	**Patent No./ Pub. No.**	**Date**	**Exhibit No.**
Edwards	US 6,024,743	Feb. 15, 2000	Ex. 1005
Ortiz	US 5,358,496	Oct. 25, 1994	Ex. 1006
Lichtman	US 5,620,459	Apr. 15, 1997	Ex. 1008
Jing	CN 1060594A	Published Apr. 29, 1992	Exs. 1010, 1011 (translation)

F. The Asserted Grounds

Petitioner challenges claims 1–15 of the '348 Patent on the following grounds (Pet. 14):

References	Basis	Claim(s) Challenged
Edwards, Ortiz, Lichtman, and Jing	§ 103(a)	1–15

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Level of Skill in the Art

Dr. Pearce testifies that a person of ordinary skill in the art

> would include someone who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices.

Ex. 1002 ¶ 47. Patent Owner does not provide evidence or argument on the level of ordinary skill. Prelim. Resp. 10 n.3. We adopt Dr. Pearce's definition for purposes of this Decision.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of

ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes express constructions for two claim terms, "frame" and "flexure." Pet. 15–17. Patent Owner does not propose an express construction for any claim term. Prelim. Resp. 8–9.

1. "frame"

Claim 1 recites "a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a *frame*" (emphasis added). Petitioner proposes to construe "frame" "to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve)." Pet. 16. Petitioner asserts that "[a]lthough 'frame' is not specifically defined, the specification does describe a 'frame member 178' mounted on the proximal grip section and enclosing various components of the handle and expansion mechanism including the 'yoke 168,' 'spring stop 172,' 'compression spring 170,' and 'hypotube 122.'" *Id.* at 15 (citing Ex. 1001, 4:28–36, 17:37–53, Fig. 34; Ex. 1002 ¶ 52). Petitioner also asserts that this construction "is

consistent with the plain and ordinary meaning of the word 'frame' as a structure that surrounds or encloses something." *Id.* at 15–16 (citing Ex. 1013, 4; Ex. 1014, 3).

On this record, we agree that the Specification uses "frame" in accordance with its ordinary meaning. *See*, *e.g.*, Ex. 1001, 17:37–49 (referring to "frame member 178" and "the frame"); Ex. 1013, 4; Ex. 1014, 3. We do not agree with Petitioner's proposed claim construction, however, because it encompasses only one (apparently, the narrower) of the two dictionary definitions of "frame" cited in the Petition. *See* Pet. 15–16 (citing Ex. 1013, 4 ("an enclosing structure or case"); Ex. 1014, 3("an arrangement of structural parts that gives form or support")). Petitioner has not explained sufficiently why the broadest reasonable claim construction should not encompass both of the dictionary definitions.

We determine that the broadest reasonable interpretation consistent with the Specification of "frame" encompasses: an arrangement of structural parts that gives form or support; and a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve).

2. flexures

Claim 1 recites "a deflecting mechanism including *flexures* disposed within the applicator head" (emphasis added"). Petitioner argues that the term "flexure" "should be construed to include a component designed to be bent or curved." *Id.* at 16–17. Petitioner asserts that its proposed claim construction is consistent with the use of "flexure" in the Specification and the term's ordinary meaning. *Id.* at 16 (citing Ex.

1001, 13:65–67, 13:56–14:31, Figs. 23, 30; Ex. 1002 ¶¶ 54–56; Ex. 1013, 3).

We do not agree with Petitioner's proposed claim construction because it is not consistent with the Specification's description of flexures 124, 136 as strips that are capable of being bent or curved. *See*, *e.g.*, Ex. 1001, 4:1–9, 13:8–14:31, Figs. 23, 28–30. Figures 23 and 28, for example, depict flexures 124 as strips that have been bent or curved as the result of relative motion between hypotubes 120 and 122. *Id.* at 13:8–15, 14:29–30, Figs. 23, 28. Indeed, Petitioner's declarant, Dr. Pearce, testifies that "a person of skill in the art would understand the term 'flexure' to refer to a component capable of being bent or curved." Ex. 1002 ¶ 56.

On this record, we determine that the broadest reasonable interpretation consistent with the Specification of "flexures" is strips that are capable of being bent or curved. We note that a distinction with Petitioner's proposed construction is that "designed to be bent," for example, could mean a structure that has been bent but is no longer bendable or a structure that is bendable. "Capable of being bent," on the other hand, means that the structure is further bendable.

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art ("POSA") to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved

obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In this case, Petitioner challenges claims 1–15 as unpatentable for obviousness over Edwards, Ortiz, Lichtman, and Jing. Pet. 14. For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

1. Overview of Asserted References

a. Edwards

Edwards "relates generally to a method and apparatus to controllably create cell necrosis of at least a portion of the uterus, and more particularly to a [a] method and apparatus to create selective cell necrosis of target sites of the uterus." Ex. 1005, 1:21–

24. Cell necrosis apparatus 10 includes expandable member 12, which is introduced into the uterus through introducer sleeve 14 "in a folded, or non-distended configuration." *Id.* at 5:4–5, 6:1–4. Following introduction, sleeve 14 is withdrawn, and expandable member 12 is expanded. *Id.* at 6:4–5. Figure 1B of Edwards is reproduced below.

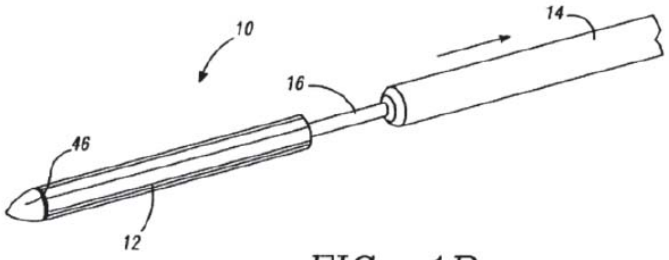


FIG. – 1B

Figure 1B is a perspective view of cell necrosis apparatus 10 in a non-deployed position as introducer sleeve 14 is withdrawn. *Id.* at 3:22–24.

Expandable member 12 can be expanded "either mechanically, with the introduction of a fluid or gaseous expanding medium, such as [an] electrolytic solution, or a combination of both." *Id.* at 6:4–8. Figure 1C is reproduced below.

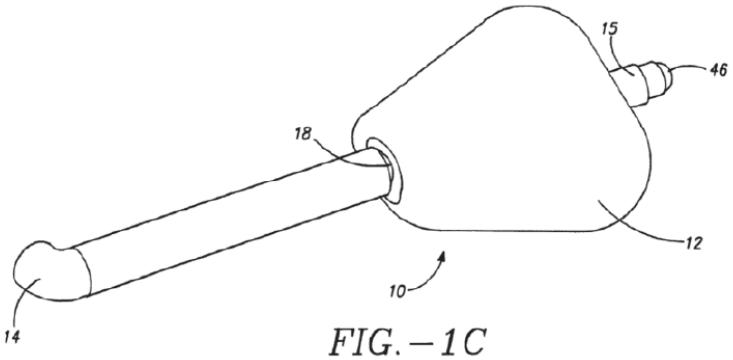


FIG.—1C

Figure 1C is a perspective view of cell necrosis apparatus 10 in a deployed position showing expandable member 12 expanded. *Id.* at 3:25–26. "Electrolytic solution is introduced into expandable member 12, causing it to become distended and be self-retained in the uterus." *Id.* at 6:10–12. In the treatment phase, "[c]ell necrosis apparatus 10 automatically conforms to the interior of the uterus." *Id.* at 6:33–34. Edwards teaches using ultrasound to create a map of the interior of the uterus:

> The amount of cell necrosis can vary. However, it is desirable to ablate about 2 to 3 mm, with approximately 1 mm of the myometrium. Ultrasound can be used to create a map of the interior of the uterus. This information is input to a controller. Individual electrodes are multiplexed and volumetrically controlled. If desired, the area of cell necrosis can be substantially the same for each cell necrosis event.

Id. at 6:48–54.

Figure 4 of Edwards is reproduced below.

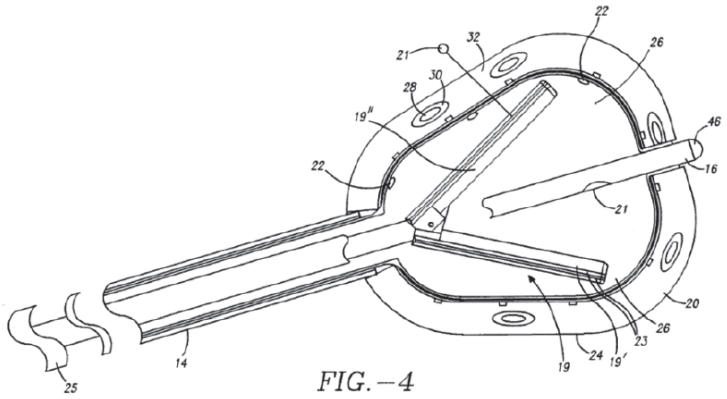
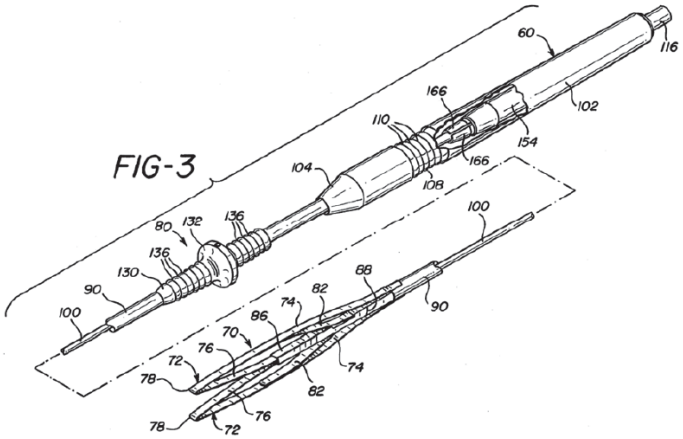


FIG.—4

Figure 4 is a cross-sectional view of an embodiment of cell necrosis apparatus 10 in which expandable member 12 is substantially surrounded by conforming member 20. *Id.* at 7:4–10. "Conforming member 20 receives electrolytic solution from expandable member 12 . . . through a plurality of apertures 22 formed in expandable member 12." *Id.* at 7:10–13. Frame 19, with arms 19', is used to assist in opening expandable member 12. *Id.* at 7:19–21. Edwards discloses that, "[i]n one embodiment, cell necrosis apparatus 10 conforms lightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20." *Id.* at 7:37–40.

b. Ortiz

Ortiz relates to an endoscopic tissue manipulator that can be inserted through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity. Ex. 1006, 1:10–12. A preferred embodiment includes a proximal handle assembly and a distal expandable platform 70. *Id.* at 4:37–39. Figure 3 of Ortiz is reproduced below:



As shown in Figure 3, platform 70 consists of a plurality of flexible, interconnected strips adapted to expand laterally outward to form a pair of fingers 72. *Id.* at 4:52–55. Each of fingers 72 comprises outer strip 74 and inner strip 76. *Id.* at 4:55–58. Outer strip 74 is attached to the distal end of actuator tube 90, and inner strip 76 is attached to the distal end of shaft or push rod 100 inside of actuator tube 90. *Id.* at 4:59–63. "[W]hen actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration." *Id.* at 5:28–31. "The outer strips 74 are pulled in the proximal direction by the actuator tube 90 and the guide tube 86 is moved proximally along the inner strips 76 by the struts 82." *Id.* at 5:32–34. Figure 7 of Ortiz is reproduced below.

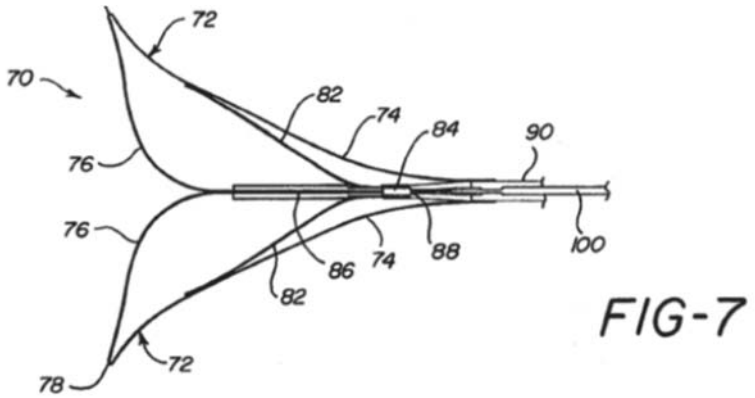


FIG-7

Figure 7 depicts a longitudinal cross section illustrating platform 70 in the tulip-shaped configuration. *Id.* at 3:29–30, 4:10–11. As shown in Figure 7, each of fingers 72 comprises flexible strut 82, having its distal end secured to outer strip 74 and its proximal end attached to connector sleeve 84, which is slidably mounted on inner strip 76. *Id.* at 4:63–5:1. Connector sleeve 84 is located within guide tube 86, which is slidably received in the distal end of actuator tube 90. *Id.* at 5:1–4. Struts 82 provide for shape control of platform 70 in its expanded configuration. *Id.* at 6:1–2. "The expanded platform 70 has a generally planar configuration which provides two flat tissue manipulating surfaces on its opposite sides." *Id.* at 8:36–39.

c. Lichtman

Lichtman discloses handle mechanisms for surgical instruments employing movable jaws, and mechanisms for moving the jaws, typically involving coaxial telescoping elements. Ex. 1008, 5:19–21, 40–42. Figure 1 of Lichtman is reproduced below.

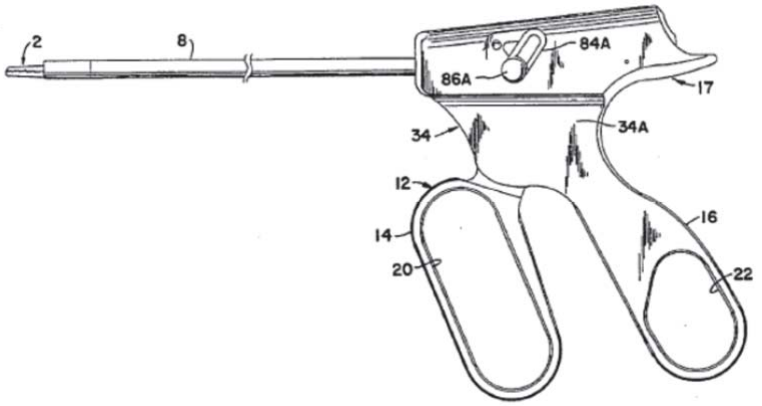


Figure 1 shows a side view of a preferred embodiment that includes unitary jaw piece 2, outer hollow shaft 8, and handle assembly 12 including stationary handle member 16 and movable handle member 14. *Id.* at 6:13–22.

Figure 9 of Lichtman is reproduced below.

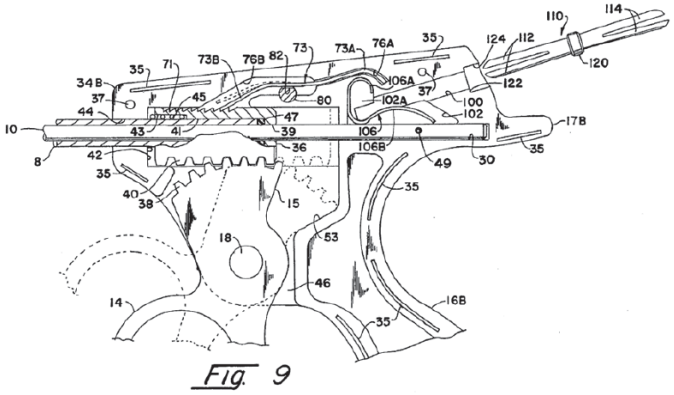


Fig. 9

Figure 9 is a partially exploded view showing outer shaft 8, inner shaft 10, and movable handle member 14, which is rotatable about pivot pin 18. *Id.* at 4:40–43, 6:15–21. Outer shaft 8, which coaxially surrounds

and is free to slide axially relative to inner tube 10, is rigidly joined to gear rack tube 36. *Id.* at 6:31–33.

d. Jing

Jing relates to a computer-controlled apparatus for measuring and displaying data of the morphology of a woman's uterine cavity. Ex. 1011, 3:5–7, 20–23, 4:25–30.[2] "An object of the present invention is to provide a computer-controlled measurement apparatus for measuring and displaying data of the morphology of the uterine cavity, thereby increasing the success rate of the IUD technique and facilitating the modification of IUDs." *Id.* at 3:20–23. Figure 2 of Jing is reproduced below.

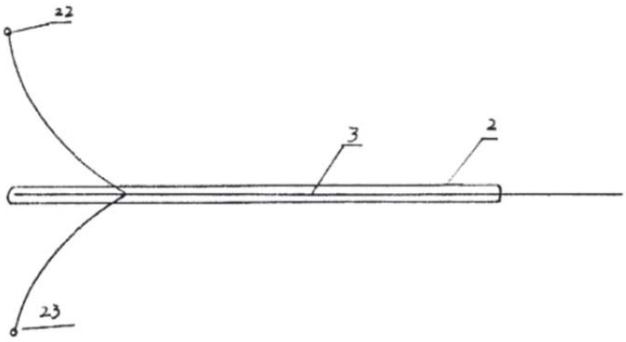


Figure 2 illustrates measuring rod 3 and dovetail-type contacts 22, 23. *Id.* at 5:9–13. Jing discloses:

> When a transverse dimension of the uterine cavity is to be measured, the measurement push button may be pushed by hand, such that two dovetail-type contacts (22, 23) of the transverse dimension measuring rod protrude from through-holes (10) at two sides of the measurement sleeve and expend [sic] to the transverse dimension

[2] We cite to the certified translation of Jing (Ex. 1011).

being measured.

Id.

2. Petitioner's Contentions with Respect to Claims 1 and 11

Petitioner argues that "Edwards on its own fully discloses" the "applicator head" limitation of claims 1 and 11. Pet. 26. While conceding that "Edwards does not specifically describe an inner sleeve slidably and coaxially disposed within an outer sleeve," as required by the "elongate member" limitation of claims 1 and 11, Petitioner contends that "these aspects are fully disclosed by Ortiz." *Id.* at 23 (citing Ex. 1002 ¶ 77). Petitioner asserts that "use of the mechanical expansion elements taught by Ortiz, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid or gaseous expansion media disclosed in Edwards because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination." *Id.* at 25 (citing Ex. 1002 ¶¶ 64, 82); *see also id.* at 53 (arguing that "a skilled artisan would also have recognized that an endometrial ablation device as in Edwards would benefit from improved contact between the expandable applicator head and the uterine wall") (citing Ex. 1002 ¶ 63).

With respect to the "deflecting mechanism" limitation requiring "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve," Petitioner again relies on Ortiz. *Id.* at 33 (citing Ex. 1002 ¶ 103). Petitioner argues that Figure 7 of Ortiz discloses first and second outer flexures ("outer strip 74") and first and second inner flexures ("flexible strut 82"). *Id.* (citing Ex. 1002 ¶ 103). Petitioner asserts that "Ortiz's deflecting

mechanism with flexures would have been a reasonable design choice enabling improved contact with the uterine wall." *Id.* at 35 (citing Ex. 1002 ¶¶ 62, 108); *see also id* at 53 ("It would have been apparent to the skilled artisan that the 'plurality of flexible, interconnected strips" and "flexible struts" taught by Ortiz would be well matched to the shape of the uterus and well suited for use as an expansion device in an endometrial ablation device.") (citing Ex. 1006 at 4:34–42, 52–55; Ex. 1002 ¶ 63). Petitioner also argues that "the combination of Edwards and Ortiz would have the added benefits of simplifying the device design by removing the need for fluid or gaseous expansion medium." *Id.* at 36 (citing Ex. 1002 ¶¶ 63–64, 108).

Petitioner contends that "Ortiz also discloses that translation of the inner sleeve (shaft 100) relative to a frame causes an applicator head to transition from a contracted to an expanded state," as required by claim 1.[3] *Id.* at 34 (citing Ex. 1002 ¶ 105). Petitioner argues:

> Ortiz discloses that "[b]y pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7)." *Id.* at 8:10-19. Since the finger slide 80 is secured to the tube 90, the shaft 100 also moves relative to the finger slide 80. Ex. 1002 ¶ 105.

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[3] We note that the claims 1 and 11 use different language to define the mechanism causing the applicator head to transition from a contracted state to an expanded state. Claim 1 recites "translating the inner sleeve relative to the frame," while claim 11 recites "translating one of the inner and outer sleeves relative to the other."

Id. at 34; *see also id.* at 51–52 (advancing similar arguments).[4] Petitioner identifies Ortiz's shaft 100 as corresponding to the "inner sleeve" and Lichtman's gear rack tube 36 as corresponding to the "frame." *Id.* at 34–35.

With respect to the requirement of claims 1 and 11 for an indicator mechanism configured to indicate a dimension of the uterus, Petitioner relies on Jing's device for measuring a transverse dimension of the uterine cavity. *Id.* at 36–38. Petitioner contends that incorporating Jing's measurement apparatus into the ablation device taught by Edwards would have allowed "measurement of a dimension of the uterus and thus the mapping expressly contemplated by Edwards." *Id.* at 37 (citing Ex. 1002 ¶¶ 111–112). Petitioner further contends that "[a] person of ordinary skill would have had reason to apply Jing's indicator mechanism to provide low cost dimension information." *Id.* at 38 (citing Ex. 1002 ¶¶ 70, 112).

Claim 11 additionally requires "when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator." Petitioner concedes that "Jing does not specifically describe whether the components receiving the dimension information would include a generator configured to deliver current to electrodes."

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[4] Petitioner similarly argues that Ortiz discloses "translating one of the inner and outer sleeves relative to the other," as required by claim 11. *Id.* at 39 ("As Dr. Pearce explains, this limitation is disclosed by Ortiz, which teaches that '[b]y pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7).'") (citing Ex. 1006 at 8:10–19; Ex. 1002 ¶ 155).

Id. at 39. Petitioner contends that "these aspects of the limitation are disclosed by Edwards." *Id.* (citing Ex. 1005, 11:34–35; Ex. 1002 ¶ 137). Petitioner argues that "addition of the dimension measuring components disclosed in Jing to the RF ablation device disclosed in Edwards would have been obvious" because "[a] person of ordinary skill in the art would have been motivated to combine Jing and Edwards in this manner in order to obtain automatic transmission of data useful for controlling the generator without requiring manual data entry, thus improving convenience." *Id.* at 40 (citing Ex. 1002 ¶ 140).

3. Patent Owner's Responsive Contentions

In response, Patent Owner argues, *inter alia*, that Petitioner has not explained sufficiently why a person of ordinary skill in the art would have combined the prior art teachings to arrive at the challenged claims as a whole. *See* Prelim. Resp. 3, 14, 57. Patent Owner asserts, for example, that Petitioner's "arguments are legally insufficient, contrary to the teachings of the prior art references, and lack any articulated reasoning with rational underpinning." *Id.* at 3.

More specifically, regarding Petitioner's asserted reasons for combining teachings of Edwards and Ortiz, Patent Owner argues that "Petitioner fails to explain how or why Ortiz's distal platform 70 improves contact with the uterine wall relative to Edwards's expandable member 12." *Id.* at 36–37. Patent Owner also challenges Petitioner's argument that "Ortiz's distal platform 70 would have 'simplif[ied] the device design by removing the need for fluid or gaseous expansion medium.'" *Id.* at 37 (citing Pet. 36). According to Patent Owner, Petitioner baselessly assumes that any combination of Ortiz with Edwards would involve a complete replacement of the fluid-actuated

components of Edwards with the mechanical components of Ortiz. *Id.* Patent Owner asserts that, contrary to Petitioner's assumption, "Edwards describes the use of mechanical components to 'assist' in the expansion of the fluid-actuated components." *Id.* Patent Owner further asserts:

> Moreover, even if the fluid-actuated components of Edwards were completely replaced by the mechanism of Ortiz, that would not simplify the device design. Ortiz's actuation mechanism requires multiple components (some fixed, some slidable), a specific handle mechanism, and a multitude of interconnected struts.

Id. at 37–38.

With respect to the limitation of claim 1 requiring a deflecting mechanism capable of "translating the inner sleeve relative to the frame," Patent Owner disputes Petitioner's contention that Ortiz's shaft 100 (the asserted "inner sleeve") is capable of translating relative to a frame. Patent Owner asserts:

> Petitioner concedes that Ortiz describes movement of actuator tube 90 relative to fixed shaft 100. (Petition at 34; *see* Ortiz col. 5:28–38 ("[W]hen actuator tube 90 is retracted, *i.e.*, moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.").) Petitioner's argument confirms that Ortiz contains an outer tube and frame that translates relative to a fixed inner shaft. This is different than the claimed requirement that the inner tube translates relative to a fixed frame.

Id. at 33–34.

With respect to the requirement of claims 1 and 11 for an indicator mechanism configured to indicate a dimension of the uterus, Patent Owner asserts that a person of ordinary skill in the art would not have combined Jing with Edwards. *Id.* at 41. Patent Owner argues, for example, that "Jing's apparatus is not . . . a low cost replacement for Edwards's ultrasound [as Petitioner contends], but rather an unnecessary additional structure that would only add to the manufacturing costs." *Id.*

Patent Owner also disputes Petitioner's arguments with respect to the additional limitation of claim 11 that "when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator." Patent Owner argues that "the width dimension provided by the Jing device is not relevant to Edwards's operation." *Id.* at 42 (citing Ex. 1005, 6:30–47); *see also id.* at 43 ("There is no evidence that the 'map' described in Edwards relates to a dimension of the uterus (*e.g.*, the width), as Petitioner asserts.").

4. Analysis

Upon consideration of the Petition and the Preliminary Response, we agree with, and adopt, Patent Owner's arguments, as summarized above, that the reasons advanced by Petitioner for combining elements of Edwards, Ortiz, Lichtman, and Jing to make the claimed invention are conclusory and insufficient, and that the asserted combination does not teach or suggest all of the claimed features. We provide additional analysis below.

As discussed above, Petitioner relies on Edwards for the "applicator head" limitation of claims 1 and 11. *See*

Pet. 26. Edwards's applicator head includes expandable member 12, into which electrolytic solution is introduced for use in ablation treatment of the uterus. *See* Ex. 1005, 6:10–12, 6:33–41, 7:4–18.

Petitioner's argument that using Ortiz's mechanical expansion elements to expand Edwards's applicator head would have simplified the device design by removing the need for a fluid or gaseous expansion medium is unpersuasive because it does not take into account that electrolytic solution is used in Edwards's applicator head, not just for expansion, but also for ablation treatment. As such, Petitioner does not explain why using Ortiz's mechanical expansion elements for expansion of Edwards's applicator head, while continuing to use electrolytic solution in the applicator head for ablation treatment, would have resulted in any simplification or benefit. Dr. Pearce's testimony that replacing the use of fluid or gaseous media with Ortiz's mechanical expansion elements would have obviated potential safety issues, such as fluid leakage or contamination, similarly fails to account for the use of electrolytic solution in Edwards's applicator head for ablation treatment and is, therefore, unpersuasive. *See* Ex. 1002 ¶ 64.

Dr. Pearce's testimony that incorporating Ortiz's expansion elements would have improved contact between Edwards's applicator head and the uterine walls is also unpersuasive. *See* Ex. 1002 ¶ 63. In particular, Dr. Pearce does not explain sufficiently why replacing the two rigid arms extending outward toward the walls of the uterus (as depicted in Figure 4 of Edwards) with the asserted flexures taught by Ortiz would have improved the ability of the device to conform to the shape of the uterus. *See id.* For example, Dr. Pearce's testimony does not address or

explain the disclosure in Edwards that "[c]ell necrosis apparatus 10 automatically conforms to the interior of the uterus." *See* Ex. 1005, 6:33–41; *see also id.* at 7:37–40 (disclosing that, in one embodiment, "cell necrosis apparatus 10 conforms lightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20").

We also are not persuaded by Petitioner's argument that Ortiz teaches or suggests the requirement of claim 1 for a deflecting mechanism capable of "translating the inner sleeve relative to the frame." *See* Pet. 34 (citing Ex. 1002 ¶105). Petitioner identifies Ortiz's shaft 100 as corresponding to the "inner sleeve" and Lichtman's gear rack tube 36 as corresponding to the "frame." *Id.* at 34–35. As disclosed in Ortiz, however, shaft 100 does not move. For example, Ortiz discloses that "when actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration." Ex. 1006, 5:28–31, Fig. 4. Similarly, Ortiz discloses: "By pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7)." *Id.* at 8:10–14. Petitioner and Dr. Pearce have not explained sufficiently how Ortiz's shaft 100, which does not move, is capable of translating relative to Lichtman's gear rack tube 36 in the asserted combination.

Further, Petitioner has not provided a sufficient rationale for combining the teachings of Jing with those of Edwards, Ortiz, and Lichtman to teach or suggest either: (1) an indicator mechanism configured to indicate a dimension of the uterus, as required by

claims 1 and 11; or (2) the additional limitation of claim 11 that "when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator." Petitioner argues that incorporating Jing's device into an endometrial ablation device as described by Edwards "would allow measurement of a dimension of the uterus and thus the mapping expressly contemplated by Edwards." Pet. 37 (citing Ex. 1002 ¶¶ 111–112). Petitioner also argues:

> Edwards expressly discloses the use of ultrasound "to create a map of the interior of the uterus" that is used to determine the appropriate parameters of the ablation treatment. Ex. 1005 at 6:50–54. A person of ordinary skill would have had reason to apply Jing's indicator mechanism to provide low cost dimension information. Ex. 1002 ¶¶ 70, 112.

Id. at 38. These arguments are conclusory, and the cited testimony from Dr. Pearce does not shed further light on why a skilled person would have combined the teachings of Jing and Edwards. *See* Ex. 1002 ¶¶ 70, 111–112. In particular, the record does not explain sufficiently why a person of ordinary skill in the art would have considered measurement of a dimension of the uterus (e.g., a transverse dimension), as taught by Jing, to constitute "the mapping expressly contemplated by Edwards," as Petitioner argues.

For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to independent claims 1 and 11 as obvious over Edwards, Ortiz, Lichtman, and Jing. As Petitioner's arguments and evidence with respect to dependent claims 2–10 and 12–15 do not remedy the deficiencies in the arguments and evidence with

respect to the independent claims, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 2–10 and 12–15.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to: claims 1–15 as obvious over Edwards, Ortiz, Lichtman, and Jing.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's Petition for an *inter partes* review of claims 1–15 of the '348 Patent is *denied*, and no *inter partes* review will be instituted pursuant to 35 U.S.C. § 314 as to any claim of the '348 Patent on any of the grounds of unpatentability alleged by Petitioner in the Petition.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

1:15-cv-1031

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

vs.

MINERVA SURGICAL, INC.,
Defendant.

MEMORANDUM AND ORDER

This matter is before the Court on defendant Minerva Surgical Inc.'s ("Minerva") renewed motion for judgment as a matter of law of no patent damages or, in the alternative, for a new trial for reasonable royalty (D.I. 521); Minerva's motion for a new trial for Lanham Act and breach of contract claims (D.I. 523); Minerva's motion for an injunction under the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2532 (D.I. 525); plaintiffs Hologic, Inc.'s and CYTYC Surgical Products, LLC's (collectively, "Hologic") motion for attorney fees and related nontaxable costs (D.I. 528); Hologic's motion for enhanced damages (D.I. 530); Hologic's motion for a permanent injunction (D.I. 532); and Hologic's motion for an accounting, supplemental damages, ongoing royalties, pre-judgment interest, and post-judgment interest (D.I. 534).

I. BACKGROUND

In this patent infringement action, Hologic alleged that Minerva infringed its patents involving a system

and method to detect uterine perforations during uterine ablation. Hologic alleged that Minerva infringed U.S. Patent No. 6,872,183 ("the '183 Patent"), titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004, and issued March 29, 2005, and U.S. Patent No. 9,095,348 ("the '348 Patent"), titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013, and issued August 4, 2015 (collectively "the Patents-in-Suit"). The '183 patent involves method claims and the asserted claim of the '348 patent is a system or apparatus claim.

Prior to trial, the Court addressed cross-motions for summary judgment on invalidity and infringement and Hologic's motion for summary judgment on the issue of assignor estoppel. Minerva asserted the patent claims at issue were invalid for lack of written description and enablement. The Court found Minerva's invalidity defenses were barred by assignor estoppel.[1] The Court also stated that even if Minerva

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[1] The determination of estoppel was based on undisputed evidence that:

> [the inventor of the '183 and '348 patents, Csaba] Truckai founded Minerva. He used his expertise to research, develop, test, manufacture, and obtain regulatory approval for the Minerva EAS. It is undisputed that Truckai's job responsibilities as Minerva's President and CEO included bringing the accused product to market to directly compete with Hologic. Hologic contends the accused product incorporates the same patented technology that Truckai's company sold to Hologic. It is undisputed that Truckai, an inventor on each of the Patents-in-Suit, executed broad assignments of his inventions to NovaCept, which was then sold to Hologic's predecessor for $325 million dollars.

D.I. 407, Memorandum and Order at 18). Hologic argued in essence "that—more than 19 years after Mr. Truckai executed his initial patent assignment—Minerva and Truckai attempt[ed] to

was not estopped from asserting the defense, its arguments lacked merit in that Minerva's Section 112 arguments rested on a flawed definition of the claims that ignored the Court's claim constructions, and Hologic had shown that the '183 and '348 patent disclosures adequately described the claims as construed by the Court (D.I. 407, at 25-26). The Court further found as a matter of law that, under the Court's claim construction, Hologic had shown that Minerva's accused product infringed the asserted claims of the patents. *Id.* at 26.

The action proceeded to trial on the patent issues of damages and willfulness and on Minerva's counterclaims for false advertising and breach of contract. Those matters were tried to a jury from July 16, 2018, to July 27, 2018. The jury found Hologic was entitled to damages for lost profits in the amount of $4,200,529.75, and for royalties not included in lost profits in the amount of $587,138.48.[2] The jury further found that Hologic's infringement was not willful. Hologic prevailed on Minerva's counterclaims—the jury rejected Minerva's counterclaims for breach of contract and false advertising under the Lanham Act violations (D.I. 498). The Court entered judgment on the verdict, subject to revision pursuant to any rulings on post-trial motions, on August 13, 2018 (D.I. 520).

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destroy the value of what Truckai sold to Hologic so that Minerva [could] directly compete with Hologic using the patented technology he already sold to Hologic." *Id.* at 18-19. The Court found that the balance of equities favored a finding of privity between Truckai and Minerva and required the application of assignor estoppel to Minerva's defenses to Hologic's patent infringement claims (*Id.* at 21).

[2] The jury verdict totaled $4,787,668.23, which Hologic argues represents an effective rate of 16.1% of total Minerva handpiece revenues.

In its pending motions, Hologic argues that this case warrants enhanced damages and asks the Court to amend the judgment by doubling Hologic's damages award of $3,752,550. Hologic contends Minerva's failure to abide by the Court's claim construction justifies enhancement and argues that Minerva should have known that its proposed claim constructions were baseless, knew that owning its own patents was no defense to infringement of Hologic's patents, knew that the presence of additional features on its device was not a defense to infringement, and should have known that it had no invalidity defense. Hologic also points to other allegedly egregious conduct by Minerva such as its failure to take remedial action, infringement after entry of judgment, its copying of the NovaSure system, and its attempts to conceal its infringement of the '348 patent by adding false statements to its operator's manual. Hologic further argues that Minerva's size and financial condition also weigh in favor of enhancement of damages.

Minerva argues in response that a finding of willfulness is a prerequisite to awarding enhanced damages under Section 284. Further, it argues that even if the Court were to consider enhancement, the evidence would not support imposition of enhanced damages under 35 U.S.C. § 284.

Hologic also moves for an award of supplemental damages from the date of the last sales records produced (April 1, 2018) to the date of judgment based on an effective royalty rate of 16.1%. It seeks an accounting and an ongoing royalty for post-judgment infringing sales at the rate of 20% plus a 10% enhancement. It also seeks prejudgment interest calculated at the prime rate compounded quarterly

from the dates of infringement through the date of judgment ($270,533) and post-judgment interest at the legal rate under 28 U.S.C. § 1961.

Minerva opposes the motion for supplemental damages and argues Hologic's calculation is not supported by any evidence. Though it concedes that Hologic is entitled to recover prejudgment interest, it urges the Court to apply the treasury bill rate. It does not challenge Hologic's right to postjudgment interest at the legal rate.

Minerva also renews its motion for JMOL, it contends the Court should award no damages to Hologic, contending that none were proven at trial. It contends the award of lost profits was improper and is not supported by evidence. It also argues Hologic failed to prove its reasonable royalty damages because the jury was not instructed to apportion the damages to reflect the infringing features of the product. Alternatively, it moves for a new trial on reasonable royalty.

Minerva also moves for a new trial on its Lanham Act and breach of contract claims. It argues that Hologic violated Federal Rule of Civil Procedure 26(e) and withheld highly relevant evidence relating to Minerva's counterclaims. It also contends the Court erred in striking and precluding testimony on the quantum of Minerva's harm resulting from false advertising and an intertwined breach of a Non-disclosure Agreement. Further, it contends the Court erred in dismissing Minerva's state-law counterclaim that Hologic falsely advertised the efficacy rates for its product. It argues that the Court's rulings made it impossible for Minerva to fully present its case on its complicated claims involving Hologic's continuous scheme to attack Minerva as a competitor with

misleading efficacy rates for products and "Scorched Earth" campaign to prevent competition.

Minerva also seeks a permanent injunction under the DTPA.[3] It seeks an order enjoining Hologic from engaging in conduct that disparages Minerva's Endometrial Ablation System ("Minerva's EAS") through their false and misleading representations about Minerva's characteristics and safety. Specifically, it moves for (1) an injunction prohibiting Hologic from disparaging the safety of Minerva's EAS, including prohibiting the use of the 20-year old liver videos that have nothing to do with Minerva's technology, and (2) a corrective disclosure to the market explaining Hologic's false and misleading use of the videos.

In response, Hologic argues that because all of Minerva's counterclaims were rejected by the jury or the Court, there is no basis for granting Minerva any equitable relief. It contends that, although the Court reserved ruling on an equitable remedy, that issue became moot when the jury returned a verdict in favor of Hologic on Minerva's Lanham Act claim.

As a threshold matter, the Court of Appeals for the Federal Circuit has now affirmed the finding by the United States Patent and Trademark Office, Patent

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[3] Minerva stated at trial that the core of its theories "are the same under the state law claims as they are under the Lanham Act." (D.I. 514, Trial Transcript (T. Tr.) at 2214) It further stated it primarily relied on the Lanham Act, but asserted the state law DTPA claim "in particular for injunctive relief." (*Id.*, T. Tr. at 2216) At the conclusion of the parties' presentation of evidence, the Court indicated dismissed the DTPA claim as it related to loss damages but reserved the issue of whether Minerva was entitled to equitable relief (i.e., an injunction) for resolution later by the Court. (*Id.*, Trial Tr. at 2217-18)

Trial and Appeal Board ("PTAB") on *inter partes* review ("IPR") that claims 1-15 of the '183 are invalid as obvious. (D.I. 614-1, Ex. A, Federal Circuit Opinion) The claims challenged in the IPR include all claims of the '183 patent Hologic asserted at trial. Minerva argues that Hologic no longer has any cause of action based on the '183 patent, and any pending litigation with respect to that patent is moot. Hologic argues that the matters are not moot unless and until the Patent Office cancels the patent.[4]

The Court finds the Federal Circuit's determination does not affect the jury verdict in this case. The jury was asked to assess damages for infringement of the asserted claims of both the '183 patent and the '348 patent, without separately apportioning damages between the asserted claims of the two patents. The jury's damages determination can be adequately supported by the finding of infringement of Claim 1 of the '348 patent. The infringement of the '348 patent apparatus claim and the '183 patent method claims were interrelated, but a finding that the method claims are not valid does not affect the finding of infringement as to the apparatus claim. In other words, one can infringe the apparatus claim even if the method claims are invalid.

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[4] The Patent Office cannot cancel claims of patents until after appeal. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 645 (Fed. Cir. 2011). Although the PTAB has been affirmed, the time to file petitions for rehearing, reconsideration and/or certiorari has not expired. Nonetheless, the Court finds it unnecessary at this point to address Hologic's motion for injunctive relief. It is not likely that the Federal Circuit will reconsider its decision or that the Supreme Court will grant certiorari. Should the decision be reversed, Hologic may again move for an injunction.

Hologic's motion for a permanent injunction against Minerva's continued infringement of the '183 patent, however, will be rendered moot by the Federal Circuit decision. Similarly, Hologic's motions for supplemental and/or enhanced damages and ongoing royalties for infringement of the '183 patent will be moot. Any supplemental or enhanced damages for infringement of the '348 patent can be awarded only up the date of expiration of the '348 patent.[5] The Federal Circuit's findings as to the '183 patent (method claims) do not affect the Court's findings of assignor estoppel on the asserted claim of the '348 patent.[6]

The Court held oral argument on the present motions on February 26, 2019. The Court has considered the record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, and finds as follows.

II. LAW

A. Standard of Review

The law of the regional circuit—here the Third Circuit—governs the standards for deciding motions for JMOL under Fed. R. Civ. P. 50(b) and new trial under Fed. R. Civ. P. 59(a). *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1325 (Fed. Cir. 2016); *Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305

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[5] The '348 Patent expired on November 19, 2018.

[6] The PTAB did not address the assignor estoppel issue. The Federal Circuit recently concluded "by allowing 'a person who is not the owner of a patent' to file an IPR, [35 U.S.C. § 311(a)] unambiguously dictates that assignor estoppel has no place in IPR proceedings." *Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 804 (Fed. Cir. 2018).

(Fed. Cir. 2012). Under Rule 50(b), in ruling on a renewed motion, "the court may: (1) allow judgment on the verdict, if the jury returned a verdict; (2) order a new trial; or (3) direct the entry of judgment as a matter of law." Fed. R. Civ. P. 50(b). A judgment as a matter of law is appropriate when "the verdict is not supported by legally sufficient evidence." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). In the Third Circuit, a "court may grant a judgment as a matter of law contrary to the verdict only if 'the record is critically deficient of the minimum quantum of evidence' to sustain the verdict." *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009) (quoting *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir.1995)).

"In considering that issue the court 'may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version.'" *Id.* (quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir.1993)). "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted). A renewed post-verdict JMOL motion under Federal Rule of Civil Procedure Rule 50(b) "may not be made on grounds not included in the earlier [Rule 50(a)] motion." *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1105 (Fed. Cir. 2003).

Federal Rule of Civil Procedure 59(e) expressly recognizes a court's authority to alter or amend its judgments. Fed. R. Civ. P. 59(e). "Consistently with

this original understanding, the federal courts generally have invoked Rule 59(e) only to support reconsideration of matters properly encompassed in a decision on the merits[,]" and legal issues collateral to the main cause of action. *White v. New Hampshire Dep't of Emp't Sec.*, 455 U.S. 445, 451 (1982). The principal limitation on that discretion is that a motion to amend "may not be granted where to do so would undermine the jury's fact-finding role and trample on the defendant's Seventh Amendment right to a jury trial." *Robinson v. Watts Detective Agency, Inc.*, 685 F.2d 729, 742 (1st Cir. 1982). Specifically, Rule 59(e) has been invoked to correct damage awards that were improperly calculated, and to include prejudgment interest to which a party was entitled. *See Lubecki v. Omega Logging, Inc.*, 674 F. Supp. 501 (W.D. Pa. 1987), *aff'd*, 865 F.2d 251 (3d Cir. 1988); 11 Wright and Miller, Federal Practice and Procedure, § 2817 n. 28–29.

The rule governing motions to alter or amend judgment is the proper basis for bringing a request for prejudgment interest. *J.A. McDonald, Inc. v. Waste Sys. Int'l Moretown Landfill, Inc.*, 247 F. Supp. 2d 542, 546 (D. Vt. 2002). The method used to calculate amount of judgment and prejudgment interest involves matters of law and is based on undisputed facts, and therefore is appropriately resolved by way of a motion to amend judgment. *Commercial Assocs. v. Tilcon Gammino, Inc.*, 801 F. Supp. 939, 942 (D.R.I. 1992), *aff'd* 998 F.2d 1092 (1st Cir. 1993).

B. Patent Damages

"To recover lost profits, 'a patent owner must prove a causal relation between the infringement and its loss of profits.'" *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1240–41 (Fed. Cir. 2017) (quoting

Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc., 246 F.3d 1336, 1353 (Fed. Cir. 2001) (internal quotation marks and citation omitted). The burden is on the patentee to show a reasonable probability that but for the infringing activity, the patentee would have made the infringer's sales. *Id.* "'There is no particular required method to prove but for causation' in patent cases." *Id.* (quoting *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017)). A useful, but non-exclusive, method to establish the patentee's entitlement to lost profits is the four-factor test articulated in *Panduit Corp. v. Stahlin Brothers Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978). *Id.* "The Panduit test requires the patentee to show: (1) 'demand for the patented product'; (2) 'absence of acceptable noninfringing substitutes'; (3) 'manufacturing and marketing capability to exploit the demand'; and (4) 'the amount of profit that . . . would have [been] made.'" *Id.* (quoting *Panduit*, 575 F.2d at 1156).

The proper inquiry under the first Panduit factor "asks whether demand existed in the marketplace for the patented product, i.e., a product 'covered by the patent in suit or that directly competes with the infringing device.'" *Id.* (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009) (internal quotation marks and citation omitted)). "All a patentee must do is 'sell[ ] some item, the profits of which have been lost due to infringing sales.'" *Id.* at 1241-42 (quoting *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1265 (Fed. Cir. 2013) (internal quotation marks and citation omitted)). "[T]he first Panduit factor 'does not require any allocation of consumer demand among the various limitations recited in a patent claim.'" *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702

F.3d 1351, 1360 (Fed. Cir. 2012) (quoting *DePuy Spine*, 567 F.3d at 1330). For purposes of the first *Panduit* factor, products are interchangeable when "the patent owner and the infringer sell products sufficiently similar to compete against each other in the same market segment." *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1219 (Fed. Cir. 1993).

With respect to the second *Panduit* factor—absence of acceptable noninfringing substitutes—a patentee need not negate every possibility, absent the infringement, that the purchaser might not have purchased a product other than its own. *Presidio Components*, 702 F.3d at 1360 (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). The patentee need only show that there was a reasonable probability that the sales would have been made "but for" the infringement. *Id.*

The Federal Circuit has held that a patent owner may satisfy the second *Panduit* element by substituting proof of its market share for proof of the absence of acceptable substitutes. *BIC Leisure Prods.*, 1 F.3d at 1219; *see, e.g.*, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1380 (Fed. Cir. 2015) (affirming analysis based on "market share" approach). This market share approach allows a patentee to recover lost profits, despite the presence of acceptable, noninfringing substitutes, because it nevertheless can prove with reasonable probability sales it would have made "but for" the infringement. *Id. Panduit's* second factor, properly applied, ensures that any proffered alternative competes in the same market for the same customers as the infringer's product. *Id.* Similarity of products is necessary in order for market share proof to show correctly

satisfaction of *Panduit's* second factor. *Id.* Consistent with Federal Circuit precedent, a patentee can reconstruct the 'but for' market by segmenting the market and determining lost profits based on its market share, assuming the patent owner and the infringer compete in the same market. *Bic Leisure*, at 1219; *see also Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378 (Fed. Cir. 2003).

C. Interest

"Prejudgment interest on a damages award for patent infringement 'is the rule' under 35 U.S.C. § 284[.]" *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1574 (Fed. Cir. 1996). The purpose of prejudgment interest is "to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655 (1983). An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment. *Id.* at 655-56. "The rate of prejudgment interest and whether it should be compounded or uncompounded are matters left largely to the discretion of the district court" and "must be guided by the purpose of prejudgment interest, which is to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." *Bio-Rad Labs., Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 969 (Fed. Cir. 1986) (internal quotation marks and citations omitted).

Regarding the rate at which prejudgment interest is calculated, the district court has the discretion to determine whether to use the prime rate, the prime rate plus a percentage, the U.S. Treasury rate ("T-bill rate"), a state statutory rate, the corporate bond rate, or whatever rate the court deems appropriate under the circumstances. *See generally Allen Archery, Inc. v. Browning Manuf. Co.*, 898 F.2d 787, 789 (Fed. Cir. 1990). "A case survey indicates that the prime rate is often selected by courts where the patentee is a large, established and credit-worthy corporation." *The Boeing Co. v. United States*, 86 Fed. Cl. 303, 323 & n.22 (Fed. Ct. Cl. 2009) (citing cases). The selection of the prime rate makes even more sense if it is consistent with the interest rate charged to the patent holder for short-term, unsecured borrowing, i.e., its cost of capital. *Id.* Similarly, courts most often compound interest, reflecting, in this regard, not only the expectation of a prudent, commercially reasonable investor, but also the way that post-judgment interest is calculated under 28 U.S.C. § 1961(c)(3). *Id.* In making a determination regarding the frequency of compounding, i.e. annually, semi-annually, quarterly, etc., courts consider how often the licensee would have made payments in accordance with the hypothetical negotiation. *See Boeing*, 86 Fed. Cl. at 323; *see Datascope*, 879 F.2d at 829 (finding no error in compounding annually); *Brunswick Corp. v. United States*, 36 Fed. Cl. 204, 219 (Fed. Cl. 1996), *aff'd*, 152 F.3d 946 (Fed. Cir. 1998) (stating that compounding interest annually is more likely to place the patentee in the same financial position it otherwise would have held had royalties been timely paid "and has expressly been approved of by the Federal Circuit"). Interest compensates the patent owner for the use of its money between the date of injury and the date of judgment.

Oiness v. Walgreen Co., 88 F.3d 1025, 1033 (Fed. Cir. 1996). In a patent case, "[g]enerally, the interest rate should be fixed as of the date of infringement, with interest then being awarded from that date to the date [the judgment is actually paid.]" *Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, No. 8:10CV187, 2016 WL 6246590, at *2 (D. Neb. May 11, 2016).

An award of prejudgment interest at the T-bill rate of 28 U.S.C. § 1961 has been held to adequately compensate a patentee. *Datascope Corp.*, 879 F.2d at 829; *see also Cornell Univ. v. Hewlett–Packard Co.*, No. 01–cv–1974, 2009 WL 1405208, at *3 (N.D.N.Y. May 15, 2009) (Rader, Fed. Cir. C.J.) ("[T]he T-bill rate has been accepted and employed by many courts in patent cases as a reasonable method of placing a patent owner in a position equivalent to where it would have been had there been no infringement"); *Enzo Biochem, Inc. v. Applera Corp.*, No. 3:04cv929 (JBA), 2014 WL 29126, at *2 (D. Conn. Jan. 3, 2014) (limiting prejudgment interest to the Treasury rate to ensure that the plaintiff did not receive "excessive compensation," noting that the plaintiff should not be "financially rewarded" for its delay); *Century Wrecker Corp. v. E.R. Buske Mfg. Co.*, 913 F. Supp. 1256, 1283 (N.D. Iowa 1996) (applying the Treasury rate rather than the prime or corporate borrowing rate as reflective of the six-year delay in filing suit). Prejudgment interest is awarded for compensatory and not punitive purposes. *Oiness*, 88 F.3d at 1033. Thus, "the merits of the infringer's challenges to the patent are immaterial in determining the amount of prejudgment interest." *Bio-Rad Labs., Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 969 (Fed. Cir. 1986).

Post judgment interest should accrue at the statutory rate as specified in 28 U.S.C. § 1961(a). *Amgen Inc. v. Hospira, Inc.*, 336 F.Supp.3d 333, at 364 (D.Del. 2018). Section 1961(a) provides, "Interest shall be allowed on any money judgment in a civil case recovered in a district court. . . . Such interest shall be calculated from the date of the entry of the judgment . . . ." 28 U.S.C. § 1961(a). Section 1961(a) does not provide for interest until a money judgment fixing the amount owed to the prevailing party. *Eaves v. Cty. of Cape May*, 239 F.3d 527, 534 (3d Cir. 2001). "The statute does not, by its terms, mandate that the judgment from which interest is calculated must be a final judgment." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1177-78 (3d Cir. 1993); *see also Skretvedt v. E.I. DuPont De Nemours*, 372 F.3d 193, 216 (3d Cir. 2004) ("The fact that the December 13, 2001, judgment was not a final order for purposes of appeal would not otherwise prevent postjudgment interest from running under § 1961 . . . .").

D. Delaware Deceptive Trade Practices Act ("DTPA")

The DTPA prohibits "disparage[ment] of the goods, services or business of another by false or misleading representations of fact," committed "in the course of a business, vocation, or occupation or that generally "creates a likelihood of confusion or of misunderstanding." 6 Del. C. §§ 2532(a)(8) & (a)(12). "The DTPA has a lower burden of proof than the Lanham Act since 'a complainant need not prove competition between the parties or actual confusion or misunderstanding' to prevail in an action under the DTPA, 6 Del. C. § 2532(b)." *Keurig, Inc. v. Strum Foods, Inc.*, 769 F. Supp. 2d 699, 712 (D. Del. 2011). The Act is intended to address unfair or deceptive trade practices that

interfere with the promotion and conduct of another's business. *Wright v. Portfolio Recovery Affiliates*, No. CIV.A. 09-612-GMS, 2011 WL 1226115, at *5 (D. Del. Mar. 30, 2011). The elements of a false advertising claim under the Lanham Act are: 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc. *CollegeSource, Inc. v. AcademyOne, Inc.*, 597 F. App'x 116, 131 (3d Cir. 2015).

E. Enhanced Damages

"[A]n award of enhanced damages requires a showing of willful infringement." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) (emphasis added); *accord i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 858 (Fed. Cir. 2010). "Awards of enhanced damages" are reserved for "egregious infringement behavior" the [Supreme] Court has "variously described . . . as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, — U.S. —, —, 136 S. Ct. 1923, 1932 (2016). In other words, reprehensible conduct undertaken with knowledge of its wrongfulness. *See id.* at 1930-32. Willfulness "is a classical jury question of intent. When trial is had to a jury, the issue should be decided by the jury." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016).

F. Attorney Fees, Nontaxable Expenses and Costs

Section 285 provides, in its entirety, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. "When deciding whether to award attorney fees under § 285, a district court engages in a two-step inquiry." *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 915 (Fed. Cir. 2012). The court first determines whether the case is exceptional and, if so, whether an award of attorney fees is justified. *Id.* at 915-16. The Supreme Court defines "an 'exceptional' case [as] simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014). An "exceptional" case is "'uncommon,' 'rare,' or 'not ordinary[.]'" *Id.* at 553. District courts may "consider a 'nonexclusive' list of 'factors,' including 'frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence.'" *Id.* at 554 n.6 (quoting *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 534 n.19 (1994)).

III. DISCUSSION

A. Minerva's Motions

1. Renewed Motion for JMOL or, Alternatively, a New Trial (D.I. 521)

The Court finds Minerva's motion for JMOL should be denied. The Court finds the evidence at trial supports the jury's determination of damages.

Hologic's damages expert, Mr. Christopher Barry presented substantial evidence of NovaSure sales. Since the parties stipulated that the NovaSure system embodies the asserted claims, NovaSure system sales alone established "demand for the patented product" under the first *Panduit* factor. Hologic need not show that the Minerva and NovaSure systems are identical. The jury was instructed that the treatments must be "sufficiently similar" to be viable alternatives in the same market (D.I. 496, Revised Initial Jury Instructions, Instruction No. 18). The jury was also instructed that "the amount of sales that Hologic lost may be shown by proving its share of the relevant market." *Id.* The record shows that Hologic's damages expert testified that he considered "alternative treatments"—such as birth control pills, IUDs, and hysterectomy—for his market share analysis but concluded those other treatments had different characteristics, belonged to a different market segment, and should not be included in the market share allocation (D.I. 509, Trial Transcript (T. Tr.) at 1053-60). Mr. Berry's analysis conformed to Federal Circuit precedent. The experts identified the pertinent market for analyzing a market share allocation was global endometrial ablation ("GEA") devices because hysterectomy, IUDs, and birth control pills are not sufficiently similar to GEA devices (D.I. 509, T. Tr. at 1056-57). The Court finds Hologic properly identified the market. Minerva's arguments against Mr. Barry's market share allocation merely goes to the weight of the evidence, which is a determination left to the jury.

The Court finds Minerva's argument that the jury failed to apportion the damages to reflect the infringing features of the product is unavailing. The jury was instructed "where there are multiple components in the accused product, patent royalty

damages must only reflect the value attributable to the infringing features of the accused product, here Minerva's EAS." D.I. 496, Revised Initial Instructions, Instruction No. 21A. The Court presumes the jury followed that instruction.

There is evidence in the record that supports the jury's calculation. The jury apparently credited some testimony from both experts, which it was entitled to do. It was ultimately up to the jury, however, to weigh the credibility of the parties' opposing theories and evidence. The Court declines to overturn a jury's determination as to the amount of a damages award when, as in this case, that verdict was supported by substantial evidence.

The Court finds Minerva's alternative motion for a new trial on reasonable royalties should also be denied. There is evidence in the record that supports the jury's royalty award. To the extent Minerva argues that the verdict form is internally inconsistent, that issue should have been raised at trial. Moreover, the Court finds the verdict form is not inconsistent. The award falls within the range of royalties the parties argued at trial. Because the verdict form did not ask the jury to specify its methodology or calculations, the Court cannot divine the method the jury used. Let it suffice to say that there are several ways it could legitimately arrived at the figure. The jury apparently credited Hologic's evidence as to comparable licenses and found that Minerva had not rebutted it. Evidence of gross profit premium also supported the jury's verdict.

2. Motion for a New Trial for Lanham Act and Breach of Contract Claims (D.I. 523)

The Court finds Minerva's motion for a new trial on its counterclaims should be denied. Though Minerva contends FDA correspondence that was allegedly withheld in discovery definitively demonstrates that Hologic's advertising for NovaSure was improper, the Court stands by its determination that the FDA correspondence was not relevant to Minerva's Lanham Act claims. Further, the Court stands by its other evidentiary rulings. The Court found there was sufficient evidence on the Lanham Act and breach of contract claims to get the claims to the jury and the jury decided against Minerva. The Court will not disturb the jury's determination.

3. Motion for an Injunction (D.I. 525)

The Court finds an injunction under the DTPA would be inappropriate in light of the jury's finding that there was no false advertising under the Lanham Act. The elements of claims for relief under the federal and state laws are sufficiently similar that the Court finds the jury's verdict is conclusive as to the state law claim as well as the federal claim. The same conduct is involved in both claims. Further, the Court finds, even if Minerva's DTPA claim had not been resolved by the jury, Minerva has not shown the irreparable harm necessary to justify injunctive relief. There is insufficient evidence of a systematic problem that would warrant an injunction in any event. The evidence at trial established that the alleged wrongful conduct was not pervasive.

B. Hologic's Motions

1. Motion for Attorney Fees and Related Nontaxable Costs (D.I. 528)

The Court finds that this is not a case so exceptional as to justify an award of such fees and expenses under 35 U.S.C. § 285. Although this patent case was hotly contested and involved numerous disputes between the parties, the record does not show that the either party adopted unreasonable or frivolous litigation positions, litigated in an unreasonable manner, or acted in bad faith. Such zealous representation is the rule, not the exception, in most patent cases.

2. Hologic's Motion for Enhanced Damages (D.I. 530)

The Court finds Hologic's motion for enhanced damages for infringement of the '183 patent is moot in view of the Federal Circuit finding of invalidity. With respect to the '348 patent, the Court finds the damages are adequate to compensate Hologic for infringement through the life of the patent.

3. Hologic's Motion for a Permanent Injunction (D.I. 532)

This motion relates only to the '183 patent and is moot.

4. Hologic's Motion for an Accounting, Supplemental Damages, Ongoing Royalties, Prejudgment Interest, and Postjudgment Interest (D.I. 534)

Hologic seeks calculation of supplemental damages from April 1, 2018 to the August 13, 2018, date of judgment. It argues that the 16.1% "effective rate," which combines both the lost profits and the reasonable royalty awarded by the jury, should be

used to calculate the supplemental damages. Minerva contends that rate is not supported by the evidence and argues that supplemental damages cannot be calculated. It argues that lost profits and reasonable royalty are two distinct damages theories and are calculated and proven in different ways.

Because the Court rejects Minerva's contention that the jury's verdict is not supported by the evidence, its argument that the jury's determination is wholly speculative is unavailing. The parties apparently agree that the jury determined the reasonable royalty rate was 8% for infringing products sold but not part of Hologic's lost profits. The jury declined to accept Minerva's contention that damages should be limited to only a reasonable royalty rate and not lost profits (D.I. 498, Jury Verdict at 1, § I.1.b). Hologic's damages expert testified that 78.6% of the products sold by Minerva represent Hologic's lost sales. Without evidence to the contrary, it is only reasonable to assume the same proportion of lost sales continued through the life of the '348 patent. The Court finds Hologic's proposal of 16.1% as a combined lost profit and reasonable royalty rate is reasonable. Accordingly, the Court finds Hologic is entitled to recover a reasonable running royalty from the last-produced date of sales (April 1, 2018) to the date the '348 patent expired (November 19, 2018). The record contains some evidence of Minerva's sales to the date of judgment, but not to the date of the expiration of the '348 patent. The Court finds Hologic is entitled to recover a 16.1% royalty for infringing sales that are not reflected in the jury verdict and the Court will order an accounting of such sales. The Court finds, however, that no enhanced royalty for infringing sales post-verdict should be awarded. Hologic has not shown that enhanced damages are warranted.

With respect to prejudgment interest, Hologic seeks prejudgment interest in the amount of $270,533, which represents interest calculated at the prime rate compounded quarterly from the date of infringement through the date of judgment. Minerva concedes Hologic is entitled to recover prejudgment interest but argues the Treasury bill ("T-bill") rate will provide adequate compensation to Hologic. The Court agrees with Hologic and finds prejudgment interest at the prime rate, compounded quarterly, from and after August of 2015 to the date of judgment is appropriate (D.I. 536, Declaration of Christopher C. Barry at 8-10; Schedule D). Accordingly, Hologic will be awarded $270,533 in prejudgment interest. There is no dispute that Hologic is also entitled to postjudgment interest and Hologic will also be awarded postjudgment at the legal rate from and after August 13, 2018. Accordingly,

IT IS ORDERED:

1. Defendant's renewed motion for judgment as a matter of law (D.I. 521) is denied.

2. Defendant's motion for a new trial (D.I. 523) is denied.

3. Defendant's motion for an injunction under the Deceptive Trade Practices Act (D.I. 525) is denied.

4. Plaintiffs' motion for attorney fees (D.I. 528) is denied.

5. Plaintiffs' motion for enhanced damages (D.I. 530) is denied.

6. Plaintiffs' motion (D.I. 532) for a permanent injunction and accounting is denied as moot.

7. Plaintiffs' motion for an accounting, supplemental damages, ongoing royalties, prejudgment interest, and postjudgment interest (D.I.

534) is granted in part and denied in part as set forth in this order.

8. Defendant shall submit an accounting of infringing sales from April 1, 2018, to November 19, 2018, within two weeks of the date of this order.

9. The parties shall each submit a proposed final judgment to the Court within three weeks of the date of this order, in conformity with this Memorandum and Order.

10. A final judgment in accordance with this Memorandum and Order will thereafter issue.

Dated this 1st day of May 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civ. No. 15-1031-JFB

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,
Plaintiffs,

vs.

MINERVA SURGICAL, INC.,
Defendant.

FINAL JUDGMENT

Pursuant to the Memorandum and Order entered on May 2, 2019 (D.I. 616) and the Jury Verdict (D.I 498),

1. Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/ counterclaimant Minerva, Inc., on plaintiffs/ counterclaim defendants claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $4,787,668.23; plus prejudgment interest in the amount of $270,533, plus postjudgment interest at the statutory rate of 2.44% under 35 U.S.C. § 1961(a).

2. Judgment is entered in favor of plaintiffs/ counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/ counterclaimant Minerva, Inc., on plaintiffs'/ counterclaim defendants' claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $1,629,304.08 in supplemental damages for Minerva's infringing sales from April 1, 2018,

through August 13, 2018, plus prejudgment interest on that amount at the prime rate compounded quarterly from the date of infringement to August 13, 2018, (D.I. 520), plus postjudgment interest thereafter at the legal rate under 28 U.S.C. § 1961 until such time as the judgment is paid.

3. Judgment is entered in favor of plaintiffs/counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc. on defendant/counterclaimant Minerva's counterclaims.

4. Defendant/counterclaimant Minerva's counterclaims are hereby dismissed.

IT IS SO ORDERED.

DATED this 31st day of May 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

BUSINESS WIRE
A Berkshire Hathaway Company
LOGO

Cytyc to Acquire Novacept in $325 Million Cash Transaction; Expands Women's Health Franchise

March 01, 2004 06:00 AM Eastern Standard Time

BOXBOROUGH, Mass.--(BUSINESS WIRE)--March 1, 2004--Cytyc Corporation (Nasdaq:CYTC), the market leader in cervical cancer screening. today announced that it has entered into a definitive merger agreement with Novacept, a privately-held company that manufactures and markets the NovaSure(TM) System. NovaSure is an innovative endometrial ablation device to treat menorrhagia, or excessive menstrual bleeding. It is estimated that in the United States alone, one in five women between the ages of 35¬55 suffers from excessive menstrual bleeding.

Under the terms of the agreement, Cytyc will acquire all of the outstanding shares and options of Novacept in exchange for approximately $325 million in cash, or $311 million net of Novacept's cash balance. Morgan Stanley is acting as financial advisor to Cytyc and has provided a commitment for up to $250 million in senior bank financing. The balance of the purchase price will be paid with Cytyc's available cash. Cytyc is also exploring other financing options. Cytyc expects the acquisition to break-even in 2004 and to be accretive to Cytyc's 2005 earnings. In addition, the transaction is expected to result in a one-time charge of approximately $20 million, largely for in-process R&D. The transaction is expected to close by the end of the first quarter of 2004 and will be subject to the satisfaction of customary closing conditions and clearance under the Hart-Scott Rodino Antitrust Improvements Act.

Patrick J. Sullivan, Cytyc's chairman, president, and chief executive officer, said, "We believe this is a great strategic opportunity for Cytyc for several reasons: First, it builds on our reputation and leadership position in providing innovative medical devices for women's health. We believe Novacept is a rapidly growing company in this space with the "best in class" device for treating women for this condition. Second, this acquisition significantly increases our sales and marketing resources to OBGYN physicians. We have approximately 100 physician sales representatives currently calling on OBGYNs. As a result of this acquisition and our 2004 growth plans, our OBGYN salesforce will double to increase our competitive position for the ThinPrep(R) Pap Test and ThinPrep(R) Imaging System as well as to marke and sell the Novacept product to our existing OBGYN customer base. This product will also leverage our international infrastructure. And third, we believe this acquisition will put us on a strong and diversified financial growth trajectory on both the top and bottom line and will position us to become a worldwide leader in providing innovative products for women's health."

Mr. Sullivan continued, "We are excited about the Novacept opportunity because we believe its patented, innovative technology for the treatment of menorrhagia offers a unique clinical solution to women who suffer from this condition. Novacept launched its NovaSure System in January 2002 and generated $38.4 million in annual sales in 2003, up from $8.3 million in sales in 2002. Reimbursement is well established nationwide. The company is cash flow positive and was profitable for the second half of 2003."

"We are very proud of our product and our accomplishments to date," said David Clapper, Novacept's

president and chief executive officer. "This merger represents an ideal fit. Our specialized expertise in this emerging market, combined with Cytyc's substantial resources and proven track record, will accelerate adoption of this important new technology, which will significantly benefit physicians and their patients. Our team is very excited to become part of Cytyc." Piper Jaffray acted as advisor to Novacept for this transaction.

It is estimated that as many as 7 million pre-menopausal women between the ages of 35-55 suffer from menorrhagia and 2.5 million women seek treatment for this condition each year. Current treatment options include hormone therapy, xystemommy, and endometrial ablation. Published studies have demonstrated the clinical efficacy of the NovaSure System and the potential cost- effectiveness of endometrial ablation compared to hysterectomy.

Mr. Sullivan concluded, "We believe this is a great strategic opportunity for Cytyc to build on our OBGYNfranohine. We will maintain the existing NovaSure sales force, which will be integrated into Cytyc's current sales organization. We plan to operate Novacept's Research and Development and Operations organizations as separate entities in Palo Alto and to continue to expand Novacept's manufacturing operation in Costa Rica. We look forward to working closely with the Novacept team to become the world-wide market leader in providing innovative products for women's health."

Cytyc management will discuss the acquisition and update earnings guidance during a conference call on March 1, at 9:00 a.m. (Eastern). Investors may access the call by dialing 877-692-2086 or 973-582- 2749. A live webcast of the call may be accessed at Cytyc's

website, http://ir.cytyc.com, and the event will be available for replay at this site approximately two hours following the call until March 15, 2004. In addition, a telephonic replay of the call will be available through March 15, 2004, by dialing 877- 519-4471 (Reservation 4564738). International callers may call 973-341-3080; reservation number is the same.

About Cytyc Corporation

Cytyc Corporation designs, develops, manufactures, and markets the ThinPrep(R) System for use in medical diagnostic applications primarily focused on women's health. The ThinPrep System is widely used for cervical cancer screening and is the platform from which the Company has launched its expansion into breast cancer risk assessment with the FirstCyte(R) Breast Test. The ThinPrep System consists of the ThinPrep(R) 2000 Processor, ThinPrep(R) 3000 Processor, ThinPrep(R) Imaging System, and related reagents, filters, and other supplies. Cytyc is traded on The Nasdaq Stock Market under the symbol CYTC.

Cytyc, ThinPrep, and FirstCyte are registered trademarks of Cytyc Corporation.

NovaSure is a trademark of Novacept.

About Novacept

Novacept designs, develops and sells medical devices for the treatment of excessive menstrual bleeding, a condition that affects one in five pre-menopausal women. Novacept sells the NovaSure Impedance Controlled Endometrial Ablation System, or the NovaSure System, which consists of a single-use device and a controller that deliver radiofrequency, or RF, energy to the uterus. The NovaSure System allows physicians to treat women with excessive menstrual bleeding in a

minimally invasive manner to eliminate or reduce their bleeding to normal levels In September 2001, the Food and Drug Administration (FDA) granted premarket approval for the NovaSure System to treat excessive menstrual bleeding due to benign causes in women for whom childbearing is complete. The product was commercially launched in the United States in early 2002. Since market introduction the company estimates that it has sold over 45,000 disposable devices, primarily to hospitals and outpatient surgery centers in the United States.

Forward-looking statements in this press release are made pursuant to the provisions of Section 21 E of the Securities Exchange Act of 1934. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements relating to the Company's financial condition, operating results and future economic performance, and management's expectations regarding future growth opportunities, product acceptance and business strategy, constitute forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from those statements. Risks and uncertainties include, among others, dependence on key personnel and proprietary technology, uncertainty of product development efforts, product acceptance, management of growth, risks associated with competition and competitive pricing pressures, risks associated with the FDA regulatory approval processes and any healthcare reimbursement policies, risks associated with litigation, and other risks detailed in the Company's filings with the Securities and Exchange Commission, including under the heading "Certain Factors Which May

Affect Future Results" in its 2003 Annual Report on Form 10-K filed with the Commission. The Company cautions readers not to place undue reliance on such forward-looking statements, which speak only as of the date they were made. The Company disclaims any to publicly update or revise any such statements to reflect any change in Company expectations or events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Contacts

Cytyc Corporation
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AGREEMENT AND PLAN OF MERGER

This Agreement and Plan of Merger (this "Agreement") is made and entered into as of March 1, 2004 (the "Agreement Date"), by and among (i) Cytyc Corporation, a Delaware corporation (the "Parent"), (ii) Radio Acquisition Corp., a California corporation and a wholly owned Subsidiary of Parent ("Merger Sub"), (iii) Novacept, a California corporation (the "Company"), and (iv) for the limited purposes of agreeing to perform the duties specified in Section 2.5, David Clapper and Edward Unkart, acting jointly as the Shareholder Representative referred to herein. Capitalized terms used herein without definition shall have the respective meanings set forth in Section 10.2 hereof.

WHEREAS, Merger Sub will merge with the Company (the "Merger"), upon the terms and subject to the conditions set forth in this Agreement and in accordance with the provisions of the California Corporations Code ("California Law");

WHEREAS, the board of directors of the Company (the "Company Board") has approved and adopted this Agreement and the consummation of the transactions contemplated hereby, and has determined to submit this Agreement and the performance of the transactions contemplated hereby to the holders (the "Company Shareholders"), of the shares of the Company's Common Stock, par value $0.001 per share (the "Company Common Stock"), and Preferred Stock, par value $0.001 per share (the "Company Preferred Stock"), for their approval in accordance with California Law; and

WHEREAS, the Company Board has carefully considered the terms of this Agreement and has determined that the terms and conditions of the transactions con-

templated hereby, including the Merger, are fair and in the best interests of, and are advisable to, the Company and the Company Shareholders, and the Company Board has recommended that the Company Shareholders vote for the approval of this Agreement and the transactions contemplated hereby.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements herein contained and intending to be legally bound hereby, Parent, Merger Sub, the Company and, for the limited purposes of agreeing to perform the duties specified in Section 2.5, the Shareholder Representative hereby agree as follows:

ARTICLE 1
THE MERGER

1.1 The Merger.

(a) Merger. Subject to the other terms and conditions of this Agreement, including those set forth in Article 7 hereof, and in accordance with California Law, at the Effective Time, Merger Sub shall be merged with and into the Company, and as a result of the Merger, the separate corporate existence of Merger Sub shall cease and the Company shall continue as the surviving corporation of the Merger (the "Surviving Corporation").

(b) Closing; Effective Time. Subject to the fulfillment or waiver of all of the conditions contained in Article 7, as soon as is reasonably practicable following the satisfaction or waiver of all of the conditions contained in Article 7, or at such other date and time as theparties hereto may agree upon, a closing (the "Closing") will be held at the offices of Bingham McCutchen LLP in East Palo Alto, California (or such other place as the parties may agree). The date on

which the Closing is actually held is referred to herein as the "Closing Date." On the Closing Date, Parent, Merger Sub and the Company shall cause the Merger to be consummated by filing an agreement of merger with the California Secretary of State, substantially in the form attached hereto as Exhibit A, and with such changes as may be made after review by the California Secretary of State (the "Merger Document"). The term "Effective Time" means the date and time of the filing of the Merger Document with the California Secretary of State (or such later time as may be agreed by each of the parties hereto and specified in the Merger Document in accordance with California Law). In the event of a conflict between the Merger Document and this Agreement, the terms of this Agreement shall govern.

1.2 Effect of the Merger. At the Effective Time, the effect of the Merger shall be as provided in the Merger Document and as provided by the applicable provisions of California Law. Without limiting the generality of the foregoing, and subject thereto, upon the consummation of the Merger, all the property (including, but not limited to, Intellectual Property and licenses to Intellectual Property), rights, privileges, powers and franchises of the Company and the Merger Sub shall vest in the Surviving Corporation, and all debts, liabilities, obligations, restrictions, disabilities and duties of each of those corporations shall become the debts, liabilities, obligations, restrictions, disabilities and duties of the Surviving Corporation.

1.3 Charter; Bylaws.

(a) At the Effective Time, the Articles of Incorporation of the Surviving Corporation (the "Surviving Corporation Charter") shall be the Articles of

Incorporation of the Company, as amended by the Merger Document.

(b) At the Effective Time, the bylaws of the Surviving Corporation shall be the bylaws of Merger Sub, as in effect immediately prior to the Effective Time, until thereafter amended as provided by California Law, the Surviving Corporation Charter and such bylaws.

1.4 Directors and Officers. The directors of Merger Sub immediately prior to the Effective Time shall be the initial directors of the Surviving Corporation, each to hold office in accordance with the Surviving Corporation Charter and the bylaws of the Surviving Corporation, and until their respective successors are duly elected and qualified or until their earlier death, disability, resignation or removal. The officers of Merger Sub immediately prior to the Effective Time shall be the initial officers of the Surviving Corporation, in each case until their respective successors are duly elected or appointed and qualified or until their earlier death, disability, resignation or removal.

1.5 Closing Date Consideration; Initial Escrow Amount; Representative Reimbursement Amount.

(a) The consideration to be paid by Parent to the Participating Rights Holders at the Closing in connection with the Merger shall be the amount of the Closing Payment Amount in cash allocated to each of such Participating Rights Holders pursuant to Section 2.1.

(b) Notwithstanding the foregoing, a portion of the Closing Payment Amount payable to the Participating Rights Holders equal to $27,500,000 (the "Initial Escrow Amount"), shall not be paid to the

Participating Rights Holders at the Closing, but shall instead be deposited with Sovereign Bank or such other escrow agent as shall be mutually agreed-upon by Parent and the Company (the "Escrow Agent"), to be held in trust by the Escrow Agent pursuant to an Escrow Agreement, substantially in the form of the attached Exhibit B, and with such changes as may be reasonably requested by the Escrow Agent (the "Escrow Agreement"), and distributed in accordance therewith. At the Closing, Parent, the Shareholder Representative and the Escrow Agent will execute and deliver the Escrow Agreement.

(c) In addition, a portion of the Closing Payment Amount otherwise payable to the Participating Rights Holders equal to $250,000 (the "Representative Reimbursement Amount"), shall not be paid to the Participating Rights Holders at the Closing, but shall instead be deposited in cash with the Shareholder Representative, to be held by the Shareholder Representative for the payment of expenses incurred by the Shareholder Representative in performing its duties pursuant to this Agreement. Any of the Representative Reimbursement Amount originally deposited with the Shareholder Representative at the Closing that has not been consumed by the Shareholder Representative pursuant to the terms of this Agreement on or prior to the end of the period in which Parent, the Surviving Corporation and their Affiliates may make claims for indemnification pursuant to Section 9.2 or, if later, the date on which all indemnification claims of Parent, the Surviving Corporation or any of their Affiliates outstanding at the end of such period have been discharged in full, shall be distributed by the Shareholder Representative to the Escrow Agent for further distribution by the Escrow Agent to the Participating Rights Holders *pro rata*

based on their respective rights to participate in receipt of the remaining Escrowed Funds, if any. Notwithstanding the delivery of any remaining portion of the Representative Reimbursement Amount to the Escrow Agent, such remaining portion shall not be deemed part of the Initial Escrow Amount or part of the Escrowed Funds and shall not be available to satisfy indemnification or other obligations to Parent hereunder.

ARTICLE 2
CONVERSION OF SECURITIES; EXCHANGE OF CERTIFICATES; PAYMENTS

2.1 Conversion of Securities.

(a) Common Stock. Each share of the Company Common Stock issued and outstanding immediately prior to the Effective Time and held by Participating Rights Holders will be converted at the Effective Time into the right to receive from Parent, in cash, an amount equal to the Per Share Common Closing Payment. All such shares of Company Common Stock, when so converted, shall no longer be outstanding and shall automatically be cancelled and retired and shall cease to exist, and each holder of a certificate representing any such shares of Company Common Stock shall cease to have any rights with respect thereto, except the right to receive the Per Share Common Closing Payment upon the surrender of such certificate in accordance with Section 2.2 and this Section 2.1. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Common Stock shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5.

(b) Preferred Stock. Each share of each series, if any, of Company Preferred Stock issued and outstanding immediately prior to the Effective Time and held by Participating Rights Holders will be converted at the Effective Time into the right to receive, in cash, an amount equal to the Per Share Preferred Closing Payment associated with such series of Company Preferred Stock. All shares of Company Preferred Stock, when so converted, shall no longer be outstanding and shall automatically be cancelled and retired and shall cease to exist, and each holder of a certificate representing any such shares of Company Preferred Stock shall cease to have any rights with respect thereto, except the right to receive the Per Share Preferred Closing Payment associated with the applicable class of Company Preferred Stock upon the surrender of such certificate in accordance with Section 2.2 and this Section 2.1. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Preferred Stock shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5. For avoidance of doubt, shares of Company Preferred Stock converted into Company Common Stock immediately prior to the Effective Time in connection with the Merger shall not be entitled to consideration under this Section 2.1(b), but instead shall be entitled to consideration on an as-converted basis as Company Common Stock pursuant to Section 2.1(a).

(c) Exchange of Options and Warrants.

(i) Options. Each option to purchase Company Common Stock issued under the Company's 1997 Stock Option Plan (the "Company Option Plan") or

otherwise listed in Section 3.2(c) of the Company Disclosure Schedule, whether or not exercisable, whether or not vested, and whether or not performance-based, which is outstanding at the Effective Time (each a "Company Option"), shall not be assumed by the Surviving Corporation or Parent, but shall instead be converted at the Effective Time into the right to receive payment as of the Closing of an amount in cash equal to the excess, if any, of the aggregate Per Share Common Closing Payment that would be payable with respect to all shares of Company Common Stock that would be issuable upon exercise of such Company Option (regardless of whether or not any such Company Option is then "vested" or exercisable) (the "Option Shares") over the aggregate exercise price per share otherwise payable by the holder thereof to acquire such Option Shares. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Options shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5.

(ii) Warrants. Any unexercised rights, warrants or options that are not described in Section 2.1(c)(i) above to purchase shares of Company Common Stock or Company Preferred Stock and that are outstanding immediately prior to the Effective Time (each a "Company Warrant") and are tendered to Parent for payment at the Closing in compliance with Section 2.2(a) shall be discharged by Parent out of the aggregate merger consideration for an amount equal to the excess, if any, of the aggregate Per Share Common Closing Payment that would be payable with respect to all shares of Company Common Stock that would be issuable upon exercise of such Company

Warrant (the "Warrant Shares") over the aggregate exercise price otherwise payable by the holder to acquire such Warrant Shares. For the purposes of the calculating the portion of the Closing Payment Amount to be paid to the holder of a Company Warrant to purchase Company Preferred Stock, such Company Warrant shall be deemed exercisable for that number of shares of Company Common Stock equal to the number of shares of Company Preferred Stock for which such Company Warrant may be exercised multiplied by the applicable conversion rate for the series of Company Preferred Stock specified in such Company Warrant. In addition, the per share exercise price for such Company Warrant shall be deemed to be the per share exercise price specified in the Company Warrant divided by the applicable conversion rate for the series of Preferred Stock specified in such Company Warrant. For avoidance of doubt, the intent of the foregoing provisions regarding Company Warrants exercisable for Company Preferred Stock is the effect the exchange of such Company Warrants for a portion of the aggregate merger consideration on an as-converted to Company Common Stock basis. Notwithstanding the foregoing, portions of the Closing Payment Amount attributable to the Company Warrants shall be deposited in escrow and a portion of the Closing Payment Amount shall be paid to the Shareholder Representative as the Representative Reimbursement Amount in accordance with Section 1.5.

(d) Treasury Stock. Each share of Company Common Stock or Company Preferred Stock held in the treasury of the Company or held by any Subsidiary of the Company immediately prior to the Effective Time shall be cancelled and extinguished at the

Effective Time without any conversion thereof and no payment shall be made with respect thereto.

(e) Stock Held by Parent. Each share of Company Common Stock or Company Preferred Stock held by Parent or any Affiliate of Parent shall be cancelled and extinguished at the Effective Time without any conversion thereof and no payment shall be made with respect thereto.

(f) Stock of Merger Sub. Each share of common stock of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into one (1) validly issued fully paid and nonassessable share of common stock of the Surviving Corporation.

2.2 Exchange of Certificates and Instruments for Closing Payment Amount.

(a) Exchange Procedures.

(i) Within a reasonable period of time prior to the Closing, Parent will deliver to the Company forms of the transmittal materials which Parent will reasonably require from those Participating Rights Holders entitled to receive a portion of the Closing Payment Amount in respect of their shares of Company Common Stock or Company Preferred Stock, or in respect of their Company Options or Company Warrants, which materials may include any certifications Parent may request with respect to compliance with any withholding obligations of Parent or the Surviving Corporation under the Code. The Company will distribute such materials to eligible Participating Rights Holders. As promptly as practicable following the Effective Time, Parent will deliver to each Participating Rights Holder who has completed such transmittal materials and returned them to Parent at or prior to the Closing, together with the certificate or

certificates representing outstanding shares of Company Common Stock or Company Preferred Stock (the "Certificates"), or certificates or instruments representing outstanding Company Options or Company Warrants ("Derivative Instruments"), a check (or, at the election of the Shareholder Representative, a wire transfer to the extent that the aggregate amount owed to any such holder is in excess of $1,000,000) representing that portion of the Closing Payment Amount that such Participating Rights Holder is entitled to receive in cash. The (i) delivery of such checks (or wire transfers, as applicable) by Parent to the Participating Rights Holders and (ii) deposit of the Initial Escrow Amount with the Escrow Agent and (iii) delivery of the Representative Reimbursement Amount to the Shareholder Representative shall be deemed, for all purposes, to have satisfied in full Parent's Closing Payment Amount obligations to such Participating Rights Holders and Parent shall have no further obligation for such payments. Parent shall not be required to pay any amount of the Closing Payment Amount to a particular Participating Rights Holder until receipt from such Participating Rights Holder of properly completed and executed transmittal materials in the form prepared by Parent. Parent shall be entitled to rely entirely on the information contained in the Capitalization Certificate and any transmittal materials delivered hereunder for purposes of satisfying Parent's obligation to deliver the Closing Payment Amount.

(ii) As promptly as practicable after the Effective Time, Parent will send to each Participating Rights Holder who does not submit completed transmittal materials to Parent at or before the Closing, as permitted by Section 2.2(a)(i) above, transmittal materials for use in exchanging his, her or its Certificates

or Derivative Instruments for the applicable portion of the Closing Payment Amount into which such shares of Company Common Stock or Company Preferred Stock (other than any Dissenting Shares) or Company Options or Company Warrants, have been converted. Until surrendered as contemplated by this Section 2.2, each Certificate or Derivative Instrument shall be deemed at any time after the Effective Time to represent only the right to receive upon such surrender the applicable portion of the Closing Payment Amount payable pursuant to Section 2.1. Upon receipt of the completed transmittal materials and the applicable Certificates and Derivative Instruments from a Participating Rights Holder, Parent will deliver to such Participating Rights Holder a check (or, at the election of the Shareholder Representative, a wire transfer to the extent that the aggregate amount owed to any such holder at the Closing is in excess of $1,000,000) representing that portion of the Closing Payment Amount that such Participating Rights Holder is entitled to receive in cash.

(b) No Further Rights in Certificates or Derivative Instruments. After the Effective Time, holders of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants outstanding immediately prior to the Effective Time will cease to be, and will have no rights as, shareholders or rightsholders of the Company or the Surviving Corporation, other than (i) in the case of Company Common Stock and Company Preferred Stock (other than Dissenting Shares), and Company Options and Company Warrants, the rights to receive the applicable portion of the Closing Payment Amount; (ii) in the case of Dissenting Shares, the rights afforded to the holders thereof under Sections 1300-1312 of California Law,

as applicable, and (iii) rights under this Agreement and the Escrow Agreement.

(c) No Liability. Neither Parent, the Surviving Corporation nor the Company shall be liable to any holder of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants for any portion of the Closing Payment Amount delivered to an appropriate public official pursuant to any abandoned property, escheat or similar law.

(d) Withholding Rights. Each of the Surviving Corporation and Parent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants such amounts as it is required to deduct and withhold with respect to the making of such payment under the Code, or any provision of state, local or foreign Tax Law. To the extent that amounts are so withheld by the Surviving Corporation or Parent, as the case may be, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to such holder in respect of which such deduction and withholding was made by the Surviving Corporation or Parent, as the case may be.

(e) Lost Instrument or Certificate Procedure. If a Certificate or Derivative Instrument held by a Participating Rights Holder has been lost, destroyed or mutilated, in lieu of receipt of the original instrument, the Parent will accept from such Participating Rights Holder a lost certificate affidavit in a form reasonably satisfactory to Parent attesting that such loss, destruction or mutilation has occurred and agreeing to indemnify and hold harmless the Parent for any losses in connection therewith.

2.3 Stock Transfer Books. At the Effective Time, the stock transfer books of the Company shall be closed and there shall be no further registration of transfers of Company Common Stock or Company Preferred Stock thereafter on the records of the Company. From and after the Effective Time, the holders of certificates representing such shares outstanding immediately prior to the Effective Time shall cease to have any rights with respect to such shares except as otherwise provided herein or by any applicable laws.

2.4 Dissenting Shares.

(a) Notwithstanding any provision of this Agreement to the contrary, shares of Company Common Stock or Company Preferred Stock that are outstanding immediately prior to the Effective Time and which are held by shareholders who shall have not voted in favor of the Merger or consented thereto in writing and who shall have exercised dissenters' rights or rights of appraisal for such shares of Company Common Stock or Company Preferred Stock in accordance with California Law, if any, and who, as of the Effective Time, have not effectively withdrawn or lost such dissenters' rights (collectively, the "Dissenting Shares"), shall not be converted into or represent the right to receive any portion of the amounts to be paid pursuant to Section 2.1, but the holders thereof shall only be entitled to such rights as are granted by California Law, if any. All Dissenting Shares held by shareholders who shall have failed to perfect or who effectively shall have withdrawn or lost their dissenters' rights shall thereupon be deemed to have been converted into and to have become exchangeable for, as of the later of the Effective Time or the occurrence of such event, the right to receive an

appropriate portion of the amounts to be paid pursuant to Section 2.1, without any interest thereon, upon surrender, in the manner provided in Section 2.2, of the Certificates that formerly evidenced such shares.

(b) The Company shall give Parent (i) prompt notice of any demands for fair value of shares of Company Common Stock or Company Preferred Stock received by the Company, withdrawals of such demands, and any other instruments served pursuant to California Law, if any, and received by the Company, and (ii) the opportunity to direct all negotiations and proceedings with respect to demands for fair value under California Law, if any. The Company shall not, except with the prior written consent of Parent, make any payment with respect to any demands for the fair value of shares of Company Common Stock or Company Preferred Stock or settle or offer to settle any such demands other than by operation of law or pursuant to a final order of a court of competent jurisdiction.

2.5 Shareholder Representative.

(a) Appointment of Shareholder Representative. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder (regardless of whether or not such Participating Rights Holder votes in favor of the adoption of the Agreement and the approval of the Merger, whether at a meeting or by written consent in lieu thereof) shall be deemed to have appointed, effective from and after the Effective Time of the Merger, David Clapper and Edward Unkart (each a "Joint Representative") to act jointly as the Shareholder Representative under this Agreement in accordance with the terms of this Section 2.5

and the Escrow Agreement. For clarity, each Joint Representative, acting jointly, shall be deemed the Shareholder Representative, and all actions required or permitted to be approved by the Shareholder Representative shall be deemed approved when approved by both Joint Representatives. If either David Clapper or Edward Unkart resigns, is removed or is no longer able to perform duties as a Joint Representative, the remaining Joint Representative shall continue as a sole Shareholder Representative, with the authority to act alone and to exercise all powers of the Shareholder Representative without the approval or joint action of another person. In the event that both David Clapper and Edward Unkart have resigned, are removed or are no longer able to perform duties as Joint Representative or as sole Shareholder Representative, as the case may be, a successor Shareholder Representative shall be selected from the following list, in the order specified, to serve as the sole Shareholder Representative, with power to act alone as the Shareholder Representative: (1) Michael Kaplan, (2) Barclay Phillips and (3) Ross Jaffee. Notwithstanding anything to the contrary in this Agreement or the Escrow Agreement: (i) unless removed, with the consent of the next enumerated successor named in the foregoing list, an outgoing sole Shareholder Representative may designate a successor Shareholder Representative different than such enumerated successor; (ii) if no enumerated successors remain in the foregoing list, an outgoing sole Shareholder Representative, unless removed, may designate a successor without the consent of any other person or Participating Rights Holder; provided, such outgoing Shareholder Representative shall use commercially reasonable efforts to provide notice of the name and address of such successor to the

Participating Rights Holders representing at least three-fourths of the Escrowed Funds then in possession of the Escrow Agent. Notwithstanding the foregoing, or anything else to the contrary in the Agreement or the Escrow Agreement, the Participating Rights Holders entitled to a majority in amount of the Escrowed Funds then in the possession of the Escrow Agent may by written action remove a Joint Representative or sole Shareholder Representative or appoint a new Shareholder Representative, whether or not named above, or may change the order of succession specified above. Any person appointed to replace a former Joint Representative or sole Shareholder Representative shall execute a statement agreeing to perform the duties set forth in this Section 2.5 and such appointment shall become effective upon delivery of such statement to the Parent and the Surviving Corporation.

(b) Authority After the Effective Time. From and after the Effective Time, the Shareholder Representative shall be authorized to:

(i) take all actions required by, and exercise all rights granted to, the Shareholder Representative in this Agreement or the Escrow Agreement;

(ii) receive all notices or other documents given or to be given to the Shareholder Representative by Parent pursuant to this Agreement or the Escrow Agreement;

(iii) negotiate, undertake, compromise, defend, resolve and settle any suit, proceeding or dispute under this Agreement or the Escrow Agreement;

(iv) execute and deliver all agreements, certificates and documents required by the Shareholder Representative in connection with any of the

transactions contemplated by this Agreement (including executing and delivering the Escrow Agreement);

(v) engage special counsel, accountants and other advisors and incur such other expenses in connection with any of the transactions contemplated by this Agreement or the Escrow Agreement;

(vi) apply the Representative Reimbursement Amount to the payment of (or reimbursement of the Shareholder Representative for) expenses and liabilities which the Shareholder Representative may incur pursuant to this Section 2.5; and

(vii) take such other action as is necessary on behalf of the Participating Rights Holders as is necessary in connection with this Agreement, the Escrow Agreement and the transactions contemplated hereby, including:

(A) taking any actions required or permitted under the Escrow Agreement; and

(B) all such other matters as the Shareholder Representative may deem necessary or appropriate to carry out the intents and purposes of this Agreement and the Escrow Agreement.

(c) Reimbursement of Expenses. The Shareholder Representative shall be entitled to receive reimbursement from any Representative Reimbursement Amounts retained on behalf of the Shareholder Representative and then, immediately prior to its distribution to the Participating Rights Holders, against the consideration held as Escrowed Funds pursuant to the Escrow Agreement, for any and all expenses, charges and liabilities, including reasonable attorneys' fees, incurred by the Shareholder Representative in the performance or discharge of its rights

and obligations under this Agreement (the "SR Expenses").

(d) Release from Liability; Indemnification; Authority of Shareholder Representative. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder shall be deemed to hereby release the Shareholder Representative from, and each Participating Rights Holder shall be deemed to have agreed to indemnify the Shareholder Representative against, liability for any action taken or not taken by him, her or it in his, her or its capacity as such agent, except for the liability of the Shareholder Representative to a Participating Rights Holder for loss which such holder may suffer from fraud committed by the Shareholder Representative in carrying out his, her or its duties hereunder. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder (regardless of whether or not such Participating Rights Holder votes in favor of the adoption of the Agreement and the approval of the Merger, whether at a meeting or by written consent in lieu thereof) shall be deemed to have appointed, as of the Agreement Date, the Shareholder Representative as his, her or its true and lawful agent and attorney-in-fact to enter into any agreement in connection with the transactions contemplated by this Agreement, to exercise all or any of the powers, authority and discretion conferred on him under any such agreement, to give and receive notices on their behalf and to be his, her or its exclusive representative with respect to any matter, suit, claim, action or proceeding arising with respect to any transaction contemplated by any such agreement, including, without limitation, the defense, settlement or compromise of any claim,

action or proceeding for which Parent or the Surviving Corporation may be entitled to indemnification. All actions, decisions and instructions of the Shareholder Representative shall be conclusive and binding upon all of the Participating Rights Holders.

(e) Acceptance. By virtue of his approval and execution of this Agreement, the Shareholder Representative hereby agrees to act as, and to undertake the duties and responsibilities of, the Shareholder Representative as set forth in this Section 2.5.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except for representations and warranties that speak as of a particular date, which representations and warranties are made only as of such particular date, the Company hereby represents and warrants to Parent as follows as of each of (a) the Agreement Date and (b) the Closing Date, subject in each case to such exceptions as are set forth in the attached Disclosure Schedule of the Company (the "Company Disclosure Schedule"). Notwithstanding any other provision of this Agreement or the Company Disclosure Schedule, each exception set forth in the Company Disclosure Schedule will be deemed to qualify only each representation and warranty set forth in this Agreement (i) that is specifically identified (by cross-reference or otherwise) in the Company Disclosure Schedule as being qualified by such exception, or (ii) with respect to which the relevance of such exception is reasonably apparent on the face of the disclosure of such exception set forth in the Company Disclosure Schedule. The Company Disclosure Schedule shall be organized by section number (e.g., 3.1, 3.2 and 3.3) and may be organized by subsection number at the election of the

Company (e.g., 3.2(b), 3.9(d) and 3.10(a)), but any disclosure made in any subsection shall be effective as disclosure for the entire section, unless disclosure by subsection is specifically required by the applicable section. Cross-references by section number shall be effective, and cross-references by subsection number shall not be required.

3.1 Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of California. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify has resulted in or could be reasonably expected to result in a Material Adverse Effect on the Company. The Company has all requisite corporate power and authority to own and operate its properties and assets, to execute and deliver this Agreement, to perform its obligations under the provisions of this Agreement, and to carry on its Principal Business as presently conducted and as the Company currently proposes it be conducted.

3.2 Capitalization and Voting Rights.

(a) The authorized capital of the Company consists of:

(i) Preferred Stock. 25,245,152 shares of Company Preferred Stock, of which 133,334 shares have been designated Series A Preferred Stock, 200,000 shares have been designated Series B Preferred Stock, 230,000 shares have been designated Series C Preferred Stock, 1,000,000 shares have been designated Series D Preferred Stock, 1,500,000 shares have been designated Series D-1 Preferred Stock, 681,818 shares have been designated Series E

Preferred Stock, 3,500,000 shares have been designated Series F Preferred Stock, 3,000,000 shares have been designated Series F-1 Preferred Stock, 6,000,000 shares have been designated Series G Preferred Stock, and 9,000,000 shares have been designated Series H Preferred Stock. The respective rights, restrictions, privileges and preferences of the Company Preferred Stock are as stated in the Restated Articles.

(ii) Common Stock. 100,000,000 shares of Company Common Stock.

(b) As of the Agreement Date, the number of shares of each series of Company Preferred Stock and of Company Common Stock issued and outstanding is set forth on Section 3.2(b) of the Company Disclosure Schedule.

(c) Except as set forth in Sections 3.2(c) or 3.2(f) of the Company Disclosure Schedule, as of the Agreement Date, there are not outstanding any options, warrants, instruments, rights (including conversion or preemptive rights and rights of first refusal), proxy or stockholder agreements, or other agreements or instruments of any kind, including convertible debt instruments, for the purchase or acquisition from the Company of any of its Securities. The Company is not a party or subject to any agreement or understanding and, to the Company's knowledge, there is no agreement or understanding between any other persons, that affects or relates to the voting or giving of written consents with respect to any Security or by a director of the Company.

(d) All of the issued and outstanding shares of the Company Common Stock and Company Preferred Stock (i) have been duly authorized and validly issued

and are fully paid and nonassessable, and (ii) were issued in compliance with all applicable state and federal laws concerning the issuance of securities.

(e) Except as set forth in the Disclosure Schedule, each series of Company Preferred Stock is presently convertible into Company Common Stock on a one-for-one basis and the consummation of the transactions contemplated hereunder will not result in any anti-dilution adjustment or other similar adjustment to the outstanding shares of Company Preferred Stock.

(f) Section 3.2(f) of the Company Disclosure Schedule sets forth the name and address of each Securityholder and the Securities beneficially owned by each Securityholder, and, in the case of options, warrants, instruments and other rights to acquire capital stock of the Company, (i) the per-share exercise price payable therefor, (ii) the number of shares of the Company's capital stock each option, warrant, instrument or other right are vested or exercisable as of the Agreement Date, (iii) whether the holder of such option, warrant, instrument or other right is an employee of the Company, (iv) whether such option, warrant, instrument or other right will survive the Effective Time, if not exercised prior thereto, and (v) whether or not any such options, warrants, instruments or other rights are intended to be "incentive stock options" as such term is defined in the Code.

3.3 Subsidiaries. Except as set forth in Section 3.3 of the Company Disclosure Schedule, the Company has no Subsidiaries. The Company does not presently own or control, directly or indirectly, any interest in any other corporation, association, partnership, limited liability company or other business entity. The

Company is not a participant in any joint venture or similar arrangement.

3.4 Authorization; Binding Obligations; Governmental Consents.

(a) Subject to the Shareholder Approval, all corporate action on the part of the Company, its officers, directors and shareholders necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations of the Company hereunder have been taken prior to the Agreement Date. This Agreement is the valid and legally binding obligation of the Company, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights, and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

(b) No consent, approval, permit, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority on the part of or with respect to the Company is required in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, except the filing of the Merger Document with the California Secretary of State and pre-merger notification filings under the HSR Act with the U.S. Department of Justice and Federal Trade Commission.

3.5 Financial Statements.

(a) The Company has made available to the Parent or its counsel, and included in the Company Disclosure Schedule are, the Financial Statements.

The Financial Statements are complete and correct in all material respects and have been prepared in accordance with GAAP, except that the unaudited financial statements do not contain footnotes required by GAAP. The Financial Statements fairly present the financial condition of the Company on a consolidated basis as of the dates and during the periods indicated therein, subject, in the case of the unaudited financial statements, to normal year-end audit adjustments which are neither individually nor in the aggregate material. The Company maintains a standard system of accounting established and administered in accordance with GAAP.

(b) Except for Indebtedness reflected in the Financial Statements, the Company and its Subsidiaries have no Indebtedness outstanding at the date hereof. The Company and its Subsidiaries are not in default with respect to any outstanding Indebtedness or any instrument relating thereto, nor is there any event which, with the passage of time or giving of notice, or both, would result in a default, and no such Indebtedness or any instrument or agreement relating thereto purports to limit the issuance of any Securities by the Company or the operation of the business of the Company. Complete and correct copies of all instruments (including all amendments, supplements, waivers and consents) relating to any Indebtedness of the Company or its Subsidiaries have been furnished to the Parent or its counsel.

3.6 Liabilities. The Company and its Subsidiaries have no liabilities or, to the knowledge of the Company, contingent liabilities not disclosed in the Financial Statements, except current liabilities incurred in the ordinary course of business consistent with past practice subsequent to the date of the latest balance

sheet included in the Financial Statements and liabilities that, individually or in the aggregate, have not resulted in or could not reasonably be expected to result in a Material Adverse Effect on the Company.

3.7 Minute Book. The minute books of the Company and its Subsidiaries made available to the Parent or its counsel contain minutes of all meetings and copies of all other actions taken by written consent in lieu of a meeting of the directors or shareholders of the Company and its Subsidiaries since the time of incorporation and reflect all transactions referred to in such minutes accurately in all material respects.

3.8 Litigation. Except as set forth in Section 3.8 of the Company Disclosure Schedule, there is no action, suit or proceeding pending or, to the knowledge of the Company, currently threatened and, to the knowledge of the Company, there is no pending or currently threatened investigation pertaining to any potential action, suit or proceeding against the Company and its Subsidiaries or any of its officers or directors. The foregoing includes, without limitation, actions, suits and proceedings pending or, to the knowledge of the Company, threatened involving the prior employment of any of the employees of the Company or its Subsidiaries, their use in connection with the Company's business of any information or techniques allegedly proprietary to any of their former employers, or their obligations under any agreements with prior employers. The Company has not received any communication from any third party that could reasonably lead the Company to believe that any such action, suit, proceeding or investigation is forthcoming. The Company and its Subsidiaries are not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or govern-

ment agency or instrumentality. There is no action, suit, or proceeding by the Company or any of its Subsidiaries currently pending or that the Company or any of its Subsidiaries intends to initiate or is investigating whether to initiate.

3.9 Intellectual Property.

(a) Section 3.9(a) of the Company Disclosure Schedule sets forth a complete and accurate list of (i) all registered Intellectual Property owned, licensed or used by the Company or any of its Subsidiaries, all applications therefor, and all written licenses and assignments (excluding assignments of patent applications by inventors to the Company) to which the Company or any of its Subsidiaries is a party, and (ii) all licenses relating to technology, know-how and processes which the Company or any of its Subsidiaries has licensed or authorized for use by others.

(b) To the knowledge of the Company, the operation of the Principal Business of the Company and its Subsidiaries as presently conducted and as the Company and its Subsidiaries currently propose it be conducted does not interfere with, conflict with, infringe upon, misappropriate or otherwise violate the Intellectual Property rights of any third party. Section 3.9(b) of the Company Disclosure Schedule sets forth a complete and accurate list of third party Intellectual Property rights for which the Company or one of its Subsidiaries has sought a legal opinion regarding any potential interference with, conflict with infringement upon, misappropriation of or other violation of such third party Intellectual Property rights by the Company or its Subsidiaries. After informally applying a similar standard to all other third party Intellectual Property rights of which the Company has knowledge, the Company has determined not to seek opinions of

counsel regarding such other third party Intellectual Property.

(c) The Company is the sole owner of the entire right, title and interest in and to all Company Owned Intellectual Property and has sufficient title, ownership or interest in and to, or has a valid license or other legal right under the Company Licensed Intellectual Property used in or necessary to the operation of its Principal Business as presently conducted and as the Company currently proposes it be conducted, subject to the terms of the license agreements governing the Company Licensed Intellectual Property.

(d) Except as set forth in Section 3.9(d) of the Company Disclosure Schedule, there are no outstanding options, licenses, or agreements of any kind relating to the Company Owned Intellectual Property and neither the Company nor any of its Subsidiaries has granted any license or other right to any third party with respect to the Company Licensed Intellectual Property or Company Owned Intellectual Property. Except as set forth in Section 3.9(d) of the Company Disclosure Schedule, neither the Company nor its Subsidiaries are bound by or a party to any options, licenses or agreements of any kind with respect to the patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses, information, proprietary rights and processes of any other person.

(e) The Company has no present knowledge from which it could reasonably conclude that the Company Owned Intellectual Property and any Intellectual Property licensed to the Company under the Company Licensed Intellectual Property, are invalid or unenforceable, and the same have not been

adjudged invalid or unenforceable in whole or in part. To the knowledge of the Company, the Company Owned Intellectual Property and the Company Licensed Intellectual Property constitute all of the Intellectual Property necessary for the operation of the Principal Business of the Company and its Subsidiaries as presently conducted and as the Company and its Subsidiaries currently propose it be conducted. To the knowledge of the Company, the Company has complied with all of its obligations of confidentiality in respect of the claimed trade secrets or proprietary information of others and knows of no violation of such obligations of confidentiality as are owed to it.

(f) Except as set forth in Section 3.9(f) of the Company Disclosure Schedule, no claims or actions have been asserted, are pending or, to the knowledge of the Company, threatened against the Company or any of its Subsidiaries (i) based upon or challenging or seeking to deny or restrict the ownership by or license rights of the Company or any of its Subsidiaries of any of the Company Owned Intellectual Property or Company Licensed Intellectual Property, (ii) alleging that any services provided by, processes used by, or products manufactured or sold by the Company or any of its Subsidiaries or the operation of the Principal Business of the Company and its Subsidiaries as presently conducted and as the Company and its Subsidiaries currently propose it be conducted, interferes with, conflicts with, infringes upon, misappropriates or otherwise violates any Intellectual Property right of any third party, or (iii) alleging that the Company Licensed Intellectual Property is being licensed or sublicensed in conflict with the terms of any license or other agreement, and, the Company has not received any communication from any third party that could reasonably lead the Company to believe that such a

claim or action is forthcoming and, to the knowledge of the Company, there is no reasonable basis for such a claim or action. The Company and its Subsidiaries have not received any offers of licenses to patents that may cover any of the Company Products.

(g) As of the Agreement Date, to the knowledge of the Company, no person is engaging or has engaged in any activity that infringes or misappropriates the Company Owned Intellectual Property or Company Licensed Intellectual Property. Neither the Company nor any of its Subsidiaries has ever delivered any communication to any party (each, a "Notified Party") that could reasonably lead any such Notified Party to believe that the Company or its Subsidiaries allege that any services provided by, processes used by, or products manufactured or sold by such Notified Party, or the operation of such Notified Party's actual or proposed business, interferes with, conflicts with, infringes upon, misappropriates or otherwise violates any Company Owned Intellectual Property or Company Licensed Intellectual Property. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated by this Agreement by the Company will not breach, violate or conflict with any instrument or agreement concerning the Company Owned Intellectual Property, will not cause the forfeiture or termination or give rise to a right of forfeiture or termination of any of the Company Owned Intellectual Property or materially impair the right of the Parent to license or dispose of, or to bring any action for the infringement of, any material Company Owned Intellectual Property.

(h) The Company has made available to the Parent or its counsel correct and complete copies of all the licenses of the Company Licensed Intellectual

Property, other than licenses of commercial off-the-shelf computer software. With respect to each such license:

(i) such license is valid and binding and in full force and effect and represents the entire agreement between the respective licensor and licensee with respect to the subject matter of such license;

(ii) such license will not cease to be valid and binding and in full force and effect on terms identical in all material respects to those currently in effect as a result of the consummation of the transactions contemplated by this Agreement, nor will the consummation of the transactions contemplated by this Agreement constitute a material breach or default under such license or otherwise so as to give the licensor or any other person a right to terminate such license;

(iii) neither the Company nor any of its Subsidiaries has (A) received any notice of termination or cancellation under such license, (B) received any notice of breach or default under such license, which breach has not been cured, or (C) granted to any other third party any rights, adverse or otherwise, under such license that would constitute a material breach of such license; and

(iv) neither the Company nor, to the knowledge of the Company, any other party to such license (including any Subsidiaries of the Company) is in material breach or default thereof, and, to the knowledge of the Company, no event has occurred that, with notice or lapse of time, would constitute such a material breach or default or permit termination, modification or acceleration under such license.

(i) Except as set forth in Section 3.9(i) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has knowledge that any of its respective employees, officers, directors, agents or consultants is (i) subject to confidentiality restrictions in favor of any third person the breach of which could subject the Company or any of its Subsidiaries to any liability, or (ii) obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with their duties to the Company or any of its Subsidiaries, as applicable, or that would conflict with the Principal Business of the Company and its Subsidiaries as the Company and its Subsidiaries currently propose it be conducted. Each employee and consultant to the Company and any of Subsidiaries of the Company has executed a proprietary information and inventions agreement in substantially the form of Exhibit C attached hereto. No current or former employee or officer of or consultant to the Company or any of its Subsidiaries that has contributed to the development of registered Company Owned Intellectual Property has excluded works or inventions made prior to his or her employment or relationship with the Company or any of its Subsidiaries from his or her assignment of inventions to the Company pursuant to such employee's, officer's or consultant's proprietary information and inventions agreement. Each of the Company and its Subsidiaries has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of its trade secrets and other confidential Intellectual Property.

(j) To the knowledge of the Company:

(i) there has been no misappropriation of any material trade secrets or other material confidential Company Owned Intellectual Property by any person;

(ii) no employee, independent contractor or agent of the Company or any of its Subsidiaries has misappropriated any trade secrets of any other person in the course of such performance as an employee, independent contractor or agent; and

(iii) no employee, independent contractor or agent of the Company or any of its Subsidiaries is in material default or breach of any term of any employment agreement, non-disclosure agreement, assignment of invention agreement or similar agreement or contract relating in any way to the protection, ownership, development, use or transfer of Company Owned Intellectual Property.

(k) To the Company's knowledge, neither the execution nor delivery of this Agreement, nor the carrying on of the Principal Business by the employees of and consultants to the Company or any of its Subsidiaries, as the case may be, nor the conduct of Principal Business of the Company and its Subsidiaries as presently conducted or as the Company and its Subsidiaries currently propose it be conducted, would, to the knowledge of the Company, conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, any contract, covenant or instrument under which any of such employees or consultants is now obligated. Except to the extent already assigned to the Company or any of its Subsidiaries, neither the Company nor any of its Subsidiaries believes that it is or will be necessary to

utilize any inventions or proprietary information of any of its respective employees (or people it currently intends to hire) made prior to their employment by the Company or any of its Subsidiaries, as the case may be.

3.10 Compliance with Other Instruments. Neither the Company nor any of its Subsidiaries are in violation or default of any provision of its Articles of Incorporation (or equivalent document) or bylaws (or equivalent document) or, to the Company's knowledge, of any provision of any federal or state statute, rule or regulation applicable to the Company or any of its Subsidiaries (excluding Environmental Laws, which are covered by Section 3.15, laws and regulations relating to Company Products, FDA matters and similar laws and regulations, which are covered by Section 3.14 and Section 3.21, laws and regulations relating to Company Benefit Plans, which are covered by Section 3.20, and Tax Law, which is covered by Section 3.24). Neither the Company nor any of its Subsidiaries are in violation or default of any mortgage, indenture, contract, agreement, instrument, judgment, order, writ, decree or contract to which it is a party or by which it is bound that has resulted in or could reasonably be expected to result in a material financial penalty or loss to the Company or would otherwise result in a Material Adverse Effect on the Company. The execution, delivery and performance of this Agreement by the Company and the consummation of the Merger, (i) will not result in any violation or default described in the preceding two sentences, (ii) result in the creation of any mortgage, pledge, lien, charge or encumbrance upon any of the properties or assets of the Company or any of its Subsidiaries, or (iii) result in the suspension, revocation, impairment, forfeiture, or non-renewal of any

material permit, license, authorization or approval applicable to the Principal Business, operations or any of the assets or properties of the Company or any of its Subsidiaries.

3.11 Agreements; Actions.

(a) Except as set forth in Section 3.11(a) of the Company Disclosure Schedule, there are no agreements, understandings or proposed transactions between the Company and any of its officers, directors, Affiliates, or any Affiliate thereof, or between any Subsidiary of the Company and any of its officers, directors or Affiliates.

(b) Section 3.11(b) of the Company Disclosure Schedule sets forth all agreements, understandings, instruments, contracts, proposed transactions, judgments, orders, writs or decrees to which the Company or any of its Subsidiaries is a party or by which it is bound that involve (i) obligations (contingent or otherwise) of, or payments to, the Company or any of its Subsidiaries in excess of $50,000, or that may not be extinguished on thirty (30) days' notice or less (other than open purchase orders and invoices for the purchase or sale of goods or services entered into in the ordinary course of business), (ii) the license, assignment or transfer of any patent, copyright, trade secret or other proprietary right to or from the Company or any of its Subsidiaries (other than licenses to the Company arising from the purchase of commercial "off the shelf' or other standard products), (iii) the manufacture, marketing, sale or distribution of any products of the Company or any of its Subsidiaries in any jurisdiction, or any restrictions on the Company's or any of its Subsidiaries' exclusive rights to develop, manufacture, assemble, distribute, market and sell its products, (iv) indemnification by the Company or any

of its Subsidiaries with respect to infringements of proprietary rights (other than indemnification obligations arising from purchase, sale, marketing, supply, manufacturing, or license agreements or similar agreements entered into in the ordinary course of business), (v) any supply agreements, or (vi) other agreements that are otherwise material to the Principal Business of the Company.

(c) The Company has delivered or has caused to be delivered to the Parent or its counsel (including in connection with the delivery of the Company's compiled response to the Parent's due diligence request list, which compiled response was delivered to the Parent and its counsel at the offices of the Company's counsel by making such compiled response available for Parent and its counsel to review and remove from such offices) correct and complete copies of each contract, agreement or other arrangement listed in Section 3.11 of the Company Disclosure Schedule, as such contracts, agreements and arrangements are amended to date. Each such contract, agreement or other arrangement is a valid, binding and enforceable obligation of the Company or any of its Subsidiaries, as applicable, and, to the knowledge of the Company, of the other party or parties thereto, and is in full force and effect. Except as set forth in Section 3.11(c) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, the other party or parties thereto, is in breach or non-compliance, or, to the knowledge of the Company, is considered to be in breach or non-compliance by the other party thereto, of any term of any such contract, agreement or other arrangement, except for breach or non-compliance that has not and could not be reasonably expected to result in a Material Adverse Effect on the Company or

result in provide any other party thereto with the right to impose a material financial penalty on the Company. Except as set forth in Section 3.11(c) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has received notice of any default or threat thereof with respect to any such contract, agreement or other arrangement and neither the Company nor any of its Subsidiaries has a reasonable basis for suspecting that any such default exists or will be forthcoming. Subject to obtaining any necessary consents by the other party or parties to any such contract, agreement or other arrangement (as further set forth in Section 3.11(c) of the Company Disclosure Schedule), no contract, agreement or other arrangement listed in Section 3.11 of the Company Disclosure Schedule includes or incorporates any provision the effect of which would be to enlarge or accelerate any obligations of the Company or any of its Subsidiaries or give additional rights to any other party thereto, or terminate or lapse by reason of, the transactions contemplated by this Agreement.

(d) For the purposes of Section 3.11(b), all liabilities, agreements, understandings, instruments, contracts and proposed transactions involving the same person (including persons the Company or any of its Subsidiaries has reason to believe are affiliated therewith) shall be aggregated for the purpose of meeting the individual minimum dollar amounts of such subsections.

3.12 Related-Party Transactions. No employee, officer, or director of or consultant to the Company or any of its Subsidiaries, as the case may be, or member of his or her immediate family is indebted to the Company or any of its Subsidiaries, nor is the Company or any of its Subsidiaries indebted (or committed

to make loans or extend or guarantee credit) to any of them other than (a) for payment of salary or fees (in the case of consultants) for services rendered, (b) reimbursement for reasonable expenses incurred on behalf of the Company or any of its Subsidiaries, and (c) for other standard employee benefits made generally available to all employees (including stock options outstanding under any stock option plan approved by the Company Board or the board of directors of any of the Company's Subsidiaries, as the case may be). To the knowledge of the Company, none of such persons has any direct or indirect ownership interest in any firm or corporation with which the Company or any of its Subsidiaries is affiliated or with which the Company or any of its Subsidiaries has a business relationship, or any firm or corporation that competes with the Company or any of its Subsidiaries, except that employees, officers or directors of the Company or any of its Subsidiaries and members of their immediate families may own stock in publicly-traded companies that may compete with the Company or any of its Subsidiaries. No member of the immediate family of any officer or director of the Company is directly or indirectly interested in any material contract with the Company. No member of the immediate family of any officer or director of any Subsidiary of the Company is directly or indirectly interested in any material contract with such Subsidiary. Except as may be disclosed in the Financial Statements, neither the Company nor any of its Subsidiaries is a guarantor or indemnitor of any Indebtedness of any other person.

3.13 Changes. Except as reflected in the Financial Statements provided to the Parent, since the end of the latest completed fiscal year of the Company, there has not been:

(a) Any change in the assets, liabilities, financial condition or operations of the Company or any of its Subsidiaries from that reflected in the Financial Statements, other than changes in the ordinary course of business consistent with past practice, none of which individually or in the aggregate has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company;

(b) Any resignation or termination of any executive officer of the Company or of any of its Subsidiaries;

(c) Any material change, except in the ordinary course of business consistent with past practice, in the contingent obligations of the Company or any of its Subsidiaries by way of guaranty, endorsement, indemnity, warranty or otherwise;

(d) Any damage, destruction or loss, whether or not covered by insurance, which has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company;

(e) Any waiver by the Company or any of its Subsidiaries of a right or of a debt owed to it (i) by a director, officer or employee or the Company or any Subsidiary of the Company or (ii) in excess of $100,000;

(f) Any direct or indirect loans made by the Company to any shareholder, employee, officer or director of the Company, or a Subsidiary of the Company to any shareholder, employee, officer or director of such Subsidiary, other than advances made in the ordinary course of business consistent with past practice;

(g) Any material change in any compensation arrangement or agreement with any employee, officer, director or shareholder of the Company or any of its Subsidiaries;

(h) Any declaration or payment of any dividend or other distribution of the assets of the Company or any of its Subsidiaries, or any repurchase of any shares of outstanding capital stock of the Company;

(i) Any labor organization activity;

(j) Any Indebtedness, obligation or liability incurred, assumed or guaranteed by the Company or any of its Subsidiaries, except those for immaterial amounts and for current liabilities incurred in the ordinary course of business consistent with past practice;

(k) Any sale, assignment, transfer or license of any patents, trademarks, copyrights, trade secrets or other intangible assets of the Company or any of its Subsidiaries;

(l) Any change in any material agreement to which the Company or any of its Subsidiaries is a party or by which it is bound which has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company;

(m) Any change in the manner, method or policies employed by the Company or its Subsidiaries in the collection of its accounts receivable; or

(n) Any other event or condition of any character that, either individually or cumulatively, has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company.

3.14 Compliance with Laws; Permits. Neither the Company nor any of its Subsidiaries is in violation of any applicable statute, rule, regulation, order, judgment, decree, writ or restriction of any domestic or foreign government or any instrumentality or agency thereof in respect of the Company Products, the conduct of its business or the ownership of its properties, including, without limitation, the Health Insurance Portability and Accountability Act of 1996, 104 P.L. 191, Subtitle F, and regulations from time to time promulgated thereunder ("HIPAA") and all other laws, statutes, rules or regulations related to the delivery of health care or health care services or the payment for health care or health care services, including any laws relating to Medicare fraud and abuse or similar state laws and regulations relating to reimbursement for medical procedures. The Company and each of its Subsidiaries has all franchises, permits, licenses and any similar authority (the "Permits") necessary for the conduct of its business as now being conducted by it. No suspension or cancellation of any of the Permits is pending or, to the knowledge of the Company, threatened.

3.15 Environmental, Zoning and Safety Laws. Except as set forth in Section 3.15 of the Company Disclosure Schedule, (a) neither the activities carried on by the Company or any of its Subsidiaries at the facilities, offices or properties leased by the Company or any of its Subsidiaries, as the case may be, nor, to the knowledge of the Company, the premises occupied by the Company or any of its Subsidiaries, are in violation of any Environmental Laws, or any other zoning, health or safety law or regulation, the violation of which has resulted in or could reasonably be expected to result in a Material Adverse Effect on the Company; (b) neither the Company nor any of its

Subsidiaries nor, to the knowledge of the Company, any owner of any real property currently occupied by the Company or any of its Subsidiaries, has received written notice from any Governmental Authority that it is in violation, or alleged violation, of, or has any liability or threatened liability under, any Environmental Laws; (c) none of the properties currently or formerly owned, leased or operated by the Company or any of its Subsidiaries (including, without limitation, soils and surface and ground waters) are contaminated with any Hazardous Substance, except to the extent as would not be reasonably likely to result in material liability to the Company or any of its Subsidiaries; (d) neither the Company nor any of its Subsidiaries is liable for any off-site contamination by Hazardous Substances, except to the extent as would not be reasonably likely to result in material liability to the Company or any of its Subsidiaries; (e) the Company and each of its Subsidiaries has all material Environmental Permits necessary for the conduct of its business as now being conducted by it; (g) the Company and each of its Subsidiaries has always been and is in compliance in all material respects with its Environmental Permits; and (h) neither the execution of this Agreement nor the consummation of the transactions contemplated hereby will require the Company or any Subsidiary to perform any investigation, remediation or other action with respect to Hazardous Substances, or to provide any notice to or consent of Governmental Authorities or third parties, pursuant to any applicable Environmental Law or Environmental Permit.

3.16 Manufacturing and Marketing Rights. Neither the Company nor any of its Subsidiaries has granted rights to manufacture, produce, assemble, license, market, or sell its products to any other person

and is not bound by any agreement that affects the Company's, or any of its Subsidiaries', exclusive right to develop, manufacture, assemble, distribute, market or sell its products.

3.17 Disclosure. Neither this Agreement (including all the exhibits and schedules hereto), nor any other statements or certificates made or delivered in connection herewith or therewith, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements herein or therein not misleading in light of the circumstances under which they were made.

3.18 First Offer Rights. Except as set forth in Section 3.18 of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has granted or agreed to grant any right of first offer with respect to any acquisition of all or substantially all of the capital stock or assets of the Company to any person. Notwithstanding anything to the contrary in this Agreement or the Company Disclosure Schedule, the execution and delivery by the Company of this Agreement and the consummation of the transactions contemplated hereby have not resulted, and will not result, in a violation or breach of any agreements identified in Section 3.18 of the Company Disclosure Schedule.

3.19 Insurance. The Company and each of its Subsidiaries has in full force and effect fire and casualty insurance policies, with extended coverage, sufficient in amount (subject to reasonable deductibles) to allow the Company or such Subsidiary to replace any of its properties that might be damaged or destroyed. The Company and each of its Subsidiaries has in full force and effect insurance, including but not limited to products liability, commercial general and

excess liability and errors and omissions insurance, in the amounts set forth in Section 3.19 of the Company Disclosure Schedule. Neither the Company nor any of the Company's Subsidiaries is in default with respect to its obligations under any insurance policy maintained by it, and neither the Company nor any of the Company's Subsidiaries has been denied insurance coverage.

3.20 Employee Benefit Plans.

(a) Identification of Plans. Except as disclosed in Section 3.20(a) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries currently maintains or contributes to, or has any outstanding liability to or in respect of or obligation under, any pension, profit-sharing, deferred compensation, bonus, stock option, employment, share appreciation right, severance, group or individual health, dental, medical, life insurance, survivor benefit, or similar plan, policy, arrangement or agreement, whether formal or informal, written or oral, for the benefit of any current or former director, officer or employee of or consultant to the Company or any of its Subsidiaries, as applicable. Each of the arrangements set forth in Section 3.20(a) of the Company Disclosure Schedule is herein referred to as an "Employee Benefit Plan".

(b) Delivery of Documents. The Company has heretofore delivered to Parent or its counsel true, correct and complete copies of each Employee Benefit Plan and, with respect to each such Employee Benefit Plan, true, correct and complete copies of (i) any associated trust, custodial, insurance or service agreements, (ii) any annual report, actuarial report, or disclosure materials (including specifically any summary plan descriptions) submitted to any gov-

ernmental agency or distributed to participants or beneficiaries thereunder in the current or any of the three (3) preceding calendar years, and (iii) the most recently received IRS determination letters, if any, and any governmental advisory opinions, rulings, compliance statements, closing agreements or similar materials specific to such Employee Benefit Plan.

(c) Compliance with Terms and Law. Each Employee Benefit Plan is and has heretofore been maintained and operated in material compliance with the terms of such Employee Benefit Plan and in material compliance with the requirements prescribed (whether as a matter of substantive law or as necessary to secure favorable tax treatment) by any and all applicable statutes, governmental or court orders, or governmental rules or regulations in effect from time to time, including ERISA and the Code, and applicable to such Employee Benefit Plan. Each Employee Benefit Plan which is intended to qualify under Section 401(a) of the Code and each trust or other entity intended to qualify as a "voluntary employee benefit association" within the meaning of Section 501(c)(9) of the Code and associated with any Employee Benefit Plan is expressly identified as such in Section 3.20(c) of the Company Disclosure Schedule and has been determined to be so qualified by the IRS (or, in the case of a 401(a) plan based upon a master and prototype or volume submitter form, the sponsor of such form has received a current advisory opinion as to the form upon which the Company is entitled to rely under applicable IRS procedures) and, to the knowledge of the Company, nothing has occurred as to each which has resulted or is likely to result in the revocation of such qualification determination or which requires or could require action under the

compliance resolution programs of the IRS to preserve such qualification.

(d) Absence of Certain Events and Arrangements. Except as set forth in Section 3.20(d) of the Company Disclosure Schedule:

(i) there is no pending or, to the knowledge of the Company, threatened legal action, proceeding or investigation, other than routine claims for benefits, concerning any Employee Benefit Plan or, to the knowledge of the Company, any fiduciary or service provider thereof and, to the knowledge of the Company, there is no basis for any such legal action or proceeding;

(ii) no liability (contingent or otherwise) to the PBGC or any multi-employer plan has been incurred by the Company or any of its ERISA Affiliates or Subsidiaries (other than insurance premiums satisfied in due course);

(iii) no reportable event, or event or condition which presents a material risk of termination by the PBGC, has occurred with respect to any Employee Benefit Plan, or any retirement plan of an ERISA Affiliate or Subsidiary of the Company, which is subject to Title IV of ERISA;

(iv) no Employee Benefit Plan nor any party in interest with respect thereof has, to the knowledge of the Company, engaged in a prohibited transaction which could subject the Company or any of its Subsidiaries directly or indirectly to liability under Section 409 or 502(i) of ERISA or Section 4975 of the Code;

(iv) no Employee Benefit Plan provides health benefits subsequent to termination of employ-

ment to employees or their beneficiaries except to the extent required by applicable state laws and Title I, Part 6 of ERISA;

(v) neither the Company nor any of its Subsidiaries has announced its intention to modify or terminate any Employee Benefit Plan or adopt any arrangement or program which, once established, would come within the definition of an Employee Benefit Plan; and

(vi) neither the Company nor any of its Subsidiaries has undertaken to maintain any Employee Benefit Plan for any period of time and each such Employee Benefit Plan is terminable at the sole discretion of the sponsor thereof, subject only to such constraints as may be imposed by applicable law and the ordinary costs of termination and cancellation of the applicable contracts.

(e) Funding of Certain Plans. With respect to each Employee Benefit Plan for which a separate fund of assets is or is required to be maintained, full and timely payment has been made of all amounts required of the Company or any of its Subsidiaries, as the case may be, under the terms of each such Employee Benefit Plan or applicable law, as applied through the Closing Date, the consummation of the Merger or a short-form merger, and no accumulated funding deficiency (as defined in Section 302 of ERISA and Section 412 of the Code), whether or not waived, exists with respect to any such Employee Benefit Plan. The current value of the assets of each such Employee Benefit Plan, as of the end of the most recently ended plan year of that Employee Benefit Plan, equals or exceeds the current value of all accrued benefits liabilities under that Employee Benefit Plan.

(f) Effect of Transactions. The execution of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, will not, by themselves or in combination in any other event (regardless of whether that other event has or will occur), result in any payment (whether of severance pay or otherwise) becoming due from or under any Employee Benefit Plan (including any employment agreement) to any current or former director, officer or employee of or consultant to the Company or any of its Subsidiaries or result in the vesting, acceleration of payment or increases in the amount of any benefit payable to or in respect of any such current or former director, officer or employee of or consultant to the Company.

(g) Multi-employer Plans. No Employee Benefit Plan is a multi-employer plan.

(h) Definitions. For purposes of this Section, "multi-employer plan", "party in interest", "current value", "reportable event" and "benefit liability" have the same meaning assigned such terms under Sections 3(37), 4043(b) or 4001(a) of ERISA, and "ERISA Affiliate" means any entity which under Section 414(b), (c), (m) or (o) of the Code is treated as a single employer with the Company, determined, however, without regard to this Agreement.

3.21 FDA and Regulatory Matters; Clinical Trials.

(a) With respect to the Company Products, (i) (A) the Company and each of its Subsidiaries has obtained all necessary and applicable approvals, clearances, authorizations, licenses and registrations required by United States or foreign governments or government agencies, including, without limitation, the CE Mark, to permit the design, development, pre-

clinical and clinical testing, manufacture, labeling, sale, distribution and promotion of the Company Products in jurisdictions where it currently conducts such activities (the "Activities to Date") with respect to each Company Product (collectively, the "Company Licenses"); (B) the Company and each of its Subsidiaries, as the case may be, is in compliance in all material respects with all terms and conditions of each Company License and with all applicable Laws pertaining to the Activities to Date with respect to each Company Product which is not required to be the subject of a Company License; (C) the Company and each of its Subsidiaries, as the case may be, is in compliance with all applicable Laws regarding registration, license, certification for each site at which a Company Product is manufactured, labeled, sold, or distributed; and (D) to the extent that any Company Product has been exported from the United States, the Company or, as applicable, a Subsidiary of the Company exporting such Company Product, has exported such Company Product in compliance in all material respects with applicable Law; (ii) all manufacturing operations performed by or on behalf of the Company or its Subsidiaries have been and are being conducted in all material respects in compliance with the Quality Systems regulations of the FDA and, to the extent applicable to the Company or any of its Subsidiaries, counterpart regulations in the European Union and all other countries where compliance is required; (iii) all non-clinical laboratory studies of Company Products under development, sponsored by the Company or any of its Subsidiaries and intended to be used to support regulatory clearance or approval, have been and are being conducted in compliance with the FDA's Good Laboratory Practice for Non-Clinical Studies regulations (21 CFR Part 58) in the United

States and, to the extent applicable to the Company or any of its Subsidiaries, counterpart regulations in the European Union and all other countries; and (iv) the Company and each of its Subsidiaries is in compliance in all material respects with all applicable reporting requirements for all Company Licenses or plant registrations described in clause (i) above, including, but not limited to, applicable adverse event reporting requirements in the United States and outside of the United States under applicable Law.

(b) The Company and each of its Subsidiaries is in compliance in all material respects with all FDA and non-United States equivalent agencies and similar state and local Laws applicable to the maintenance, compilation and filing of reports, including medical device reports, with regard to the Company Products. Section 3.21(b) of the Company Disclosure Schedule sets forth a list of all applicable adverse event reports related to the Company Products, including any Medical Device Reports (as defined in 21 CFR 803). Set forth on Section 3.21(b) of the Company Disclosure Schedule are complaint review and analysis reports of the Company and each of its Subsidiaries through the date hereof, including information regarding complaints, categorized by product and root cause analysis of closed complaints, which reports are correct in all material respects.

(c) Except as set forth in Section 3.21(c) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has received any written notice or other written communication from the FDA or any other Governmental Authority (i) contesting the pre-market clearance or approval of, the uses of or the labeling and promotion of any of the Products, or

(ii) otherwise alleging any violation of any Laws by the Company or any of its Subsidiaries.

(d) There have been no recalls, field notifications or seizures ordered or adverse regulatory actions taken (or, to the knowledge of the Company, threatened) by the FDA or any other Governmental Authority with respect to any of the Company Products, including any facilities where any Company Products are produced, processed, packaged or stored and neither the Company nor any of its Subsidiaries has within the last three (3) years, either voluntarily or at the request of any Governmental Authority, initiated or participated in a recall of any Company Product.

(e) The Company and each of its Subsidiaries have conducted all of their clinical trials with reasonable care and in accordance with all applicable Laws and the stated protocols for such clinical trials.

(f) All filings with and submissions to the FDA and any similar regulatory entity in any other jurisdiction made by the Company or any of its Subsidiaries with regard to the Company Products, whether oral, written or electronically delivered, were true, accurate and complete in all material respects as of the date made, and, to the extent required to be updated, have been updated to be true, accurate and complete in all material respects as of the date of such update, and to the knowledge of the Company such filings, submissions and updates comply with all regulations of the FDA or such similar regulatory entity regarding material misstatements and omissions to state material facts.

3.22 Brokers; Expenses. The Company and its Subsidiaries have not incurred, nor will they incur,

any liability for brokerage or finders' fees or agents' commissions or investment bankers' fees or any similar charges in connection with this Agreement or the consummation of the transactions contemplated hereby, other than the investment bankers' fees payable to Piper Jaffray that will be described in the Transaction Cost Certificate.

3.23 Consents. Except for approvals contemplated by this Agreement, including without limitation, (i) the Shareholder Approval, (ii) approvals and consents, which, if not secured, would not result in a material liability to the Company or its Subsidiaries and would not result in a Material Adverse Effect on the Company, and (iii) the other consents and approvals set forth in Section 3.23 of the Company Disclosure Schedule, no permit, approval, authorization or consent of any person (excluding governmental authorities) is required in connection with the execution, delivery and performance by the Company of this Agreement or the consummation of the transactions contemplated hereby, including the consummation of the Merger.

3.24 Taxes.

(a) Filing of Tax Returns and Payment of Taxes. The Company and each of its Subsidiaries has timely filed all material Tax Returns required to be filed by it, each such Tax Return has been prepared in compliance with all applicable laws and regulations, and all such Tax Returns are true, correct and complete in all respects. All Taxes that have become due and payable by the Company or any of its Subsidiaries (whether or not shown on any Tax Return) have been paid. Neither the Company nor any Subsidiary is or will be liable for any additional Taxes in respect of any Taxable period, or any portion

thereof, ending on or before the date of the unaudited consolidated financial statements forming part of the Financial Statements included in the Company Disclosure Schedule in an amount that exceeds the corresponding reserve therefor, as reflected in such Financial Statements. Any Taxes of the Company or any of its Subsidiaries arising after such date and at or before the Effective Time have been or will be incurred in the ordinary course of the business of the Company or the applicable Subsidiary. The Company has made available to the Parent or its counsel true, correct and complete copies of all Tax Returns with respect to income Taxes filed by or with respect to the Company and/or any of its Subsidiaries with respect to Taxable periods ended on or after December 31, 1999 (the "Recent Tax Returns"), and has made available to the Parent or its counsel all relevant documents and information with respect thereto, including without limitation work papers, records, examination reports, and statements of deficiencies proposed, assessed against or agreed to by the Company or any of its Subsidiaries.

(b) Deficiencies. No deficiency or adjustment in respect of Taxes has been proposed, asserted or assessed by any Taxation Authority against the Company or any of its Subsidiaries. There are no outstanding refund claims with respect to any Tax or Tax Return of the Company or any of its Subsidiaries.

(c) Liens. There are no liens for Taxes (other than Taxes not yet due and payable) on any of the assets of the Company or any of its Subsidiaries.

(d) Extensions to Statute of Limitations for Assessment of Taxes. Neither the Company nor any Subsidiary has consented to extend the time in which

any Tax may be assessed or collected by any Taxation Authority.

(e) Extensions of the Time for Filing Tax Returns. Neither the Company nor any Subsidiary has requested or been granted an extension of the time for filing any Tax Return that has not yet been filed.

(f) Pending Proceedings. There is no action, suit, Taxation Authority proceeding, or audit with respect to any Tax now in progress, pending or, to the knowledge of the Company, threatened against or with respect to the Company or any of its Subsidiaries.

(g) No Failures to File Tax Returns. No claim has ever been made by a Taxation Authority in a jurisdiction where the Company or any of its Subsidiaries does not pay Tax or file Tax Returns that the Company or any of its Subsidiaries that does not pay Tax or file Tax Returns in such jurisdiction is or may be subject to Taxes assessed by such jurisdiction.

(h) Tax Attributes, Etc. The Company has made available to Parent a report prepared by Ernst & Young, LLP regarding the impact of Sections 382 and 383 on the Company's net operating loss and credit carryforwards. The Company has reviewed such report and has no knowledge that any fact provided to Ernst & Young LLP by the Company in connection therewith is incorrect in any material respect.

(i) Elections. All elections with respect to Taxes affecting the Company that were not made in the Recent Tax Returns are described in Section 3.24(i) of the Company Disclosure Schedule.

(j) Membership in Affiliated Groups, Liability for Taxes of Other Persons, Etc. Neither the Company nor any of its Subsidiaries has ever been a member of

any affiliated group of corporations (as defined in Section 1504(a) of the Code), other than a group having the Company as the common parent. Neither the Company nor any of its Subsidiaries has ever filed or been included in a combined, consolidated or unitary Tax Return, other than a return filed for a group having the Company as the common parent. Neither the Company nor any of its Subsidiaries is a party to or bound by any Tax sharing or allocation agreement. Neither the Company nor any of its Subsidiaries is presently liable or has any potential liability for Taxes of any person other than the Company and its Subsidiaries (i) under Treasury Regulations Section 1.1502-6 (or comparable provision of state, local or foreign law), (ii) as transferee or successor, or (iii) by contract or indemnity or otherwise.

(k) Adjustments under Section 481. Neither the Company nor any of its Subsidiaries will be required, as a result of a change in method of accounting for any period ending on or before or including the Effective Time, to include any adjustment under Section 481(c) of the Code (or any similar or corresponding provision or requirement under any other Tax Law) in Taxable income for any period ending on or after the Effective Time.

(l) Withholding Taxes. The Company and each of its Subsidiaries has, to the knowledge of the Company, timely withheld and timely paid all Taxes which are required to have been withheld and paid by it in connection with amounts paid or owing to any employee, independent contractor, creditor or other person.

(m) U.S. Real Property Holding Corporation. Neither the Company nor any of its Subsidiaries is or

has been a United States real property holding corporation within the meaning of Code Section 897(c)(2), during the applicable period specified in Code Section 897(c)(1)(A)(ii).

(n) Safe Harbor Lease Property. None of the property owned or used by the Company or any of its Subsidiaries is subject to a Tax benefit transfer lease executed in accordance with Section 168(0(8) of the Internal Revenue Code of 1954, as amended by the Economic Recovery Tax Act of 1981.

(o) Tax-Exempt Use Property. None of the property owned by the Company or any of its Subsidiaries is "tax-exempt use property" within the meaning of Section 168(h) of the Code.

(p) Security for Tax-Exempt Obligations. None of the assets of the Company or any of its Subsidiaries directly or indirectly secures any Indebtedness, the interest on which is tax-exempt under Section 103(a) of the Code, and neither the Company nor any Subsidiary is directly or indirectly an obligor or a guarantor with respect to any such Indebtedness.

(q) Parachute Payments, Etc. Neither the Company nor any Subsidiary has made any payments, is obligated to make any payments, or is a party to any agreement that under certain circumstances could obligate it to make any payments to an employee or independent contractor in connection with the transactions contemplated by this Agreement, that are not or would not be deductible under Section 280G of the Code. Neither the Company nor any Subsidiary has made any payments or is obligated to make any payments that are not or would not be deductible under Section 162(m) of the Code.

(r) Rulings. The Company has made available to the Parent or its counsel copies of all rulings (if any) issued to the Company by any Taxation Authority, and copies of all outstanding requests for rulings that have been submitted by the Company to any Taxation Authority.

(s) Divisive Transactions. Neither the Company nor any Subsidiary has ever been either a "distributing corporation" or a "controlled corporation" in connection with a distribution of stock qualifying for tax-free treatment, in whole or in part, pursuant to Section 355 of the Code.

(t) Operations Outside the United States. Neither the Company nor any of its Subsidiaries is subject to Tax in any jurisdiction in which it does not file Tax Returns.

3.25 Employees. The Company has no collective bargaining agreements with any of its employees. There is no labor union organizing activity pending or, to the Company's knowledge, threatened with respect to the Company or any of its Subsidiaries. To the Company's knowledge, no employee of the Company or its Subsidiaries, nor any consultant with whom the Company or any of its Subsidiaries has contracted, is in violation of any term of any employment contract, proprietary information agreement or any other agreement relating to the right of any such individual to be employed by, or to contract with, the Company and its Subsidiaries because of the nature of the business to be conducted by the Company; and to the Company's knowledge, the continued employment by the Company and its Subsidiaries of its present employees, and the performance of the Company's contracts with its independent contractors, will not result in any such violation. Neither the Company nor

any of its Subsidiaries has received any notice alleging that any such violation has occurred. No employee of the Company or any of its Subsidiaries has been granted the right to continued employment by the Company.

3.26 Obligations of Management. To the knowledge of the Company, each officer of the Company and its Subsidiaries is currently devoting one hundred percent (100%) of his or her business time to the conduct of the business of the Company. To the knowledge of the Company, no officer of the Company or any of its Subsidiaries is planning to work less than full time at the Company or any of its Subsidiaries in the future.

3.27 Title to Properties and Assets; Liens, Etc. The Company and each of its Subsidiaries has good and valid title to all of its properties and assets, including the properties and assets reflected in the most recent balance sheet included in the Financial Statements, and good title to its leasehold estates, in each case subject to no mortgage, pledge, lien, lease, encumbrance or charge, other than (a) those resulting from Taxes which have not yet become delinquent, (b) minor liens and encumbrances not materially impair the operations of the Company, and (c) those that have otherwise arisen in the ordinary course of business. All facilities, machinery, equipment, fixtures, vehicles and other properties owned, leased or used by the Company and its Subsidiaries are reasonably fit and usable for the purposes for which they are being used.

ARTICLE 4
REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Parent and Merger Sub, jointly and severally, hereby represent and warrant to the Company as of the Agreement Date, and as of the Closing Date, as follows, subject in each case to such exceptions as are specifically contemplated by this Agreement:

4.1 Organization, Good Standing and Qualification. Parent is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Merger Sub is a corporation duly organized, validly existing and in good standing under the laws of the State of California. Each of Parent and Merger Sub has all requisite corporate power and authority to own and operate its properties and assets, to execute and deliver this Agreement, to carry out the provisions of this Agreement and the Escrow Agreement and to perform its obligations under, and carry out the provisions of, this Agreement and the Escrow Agreement, and to carry on its principal business as presently conducted and as presently proposed to be conducted. Parent is duly qualified to transact business and is in good standing in each jurisdiction where such qualification is required and in which failure to so qualify would result in or could be reasonably expected to result in a Material Adverse Effect on Parent.

4.2 Authorization; Binding Obligations; Governmental Consents.

(a) All corporate actions on the part of Parent and Merger Sub, and their respective officers, directors and shareholders necessary for the authorization of this Agreement and the Escrow Agreement and the

performance of all obligations of Parent and Merger Sub hereunder and thereunder have been taken. This Agreement is and, once executed and delivered by Parent in accordance with the terms hereof, the Escrow Agreement will be, the valid and binding obligations of Parent and Merger Sub, enforceable against such parties in accordance with their respective terms, except as such enforcement may be limited by (i) the effect of bankruptcy, insolvency, reorganization, receivership, conservatorship, arrangement, moratorium or other laws affecting or relating to the rights of creditors generally, or (ii) the rules governing the availability of specific performance, injunctive relief or other equitable remedies and general principles of equity, regardless of whether considered in a proceeding in law or equity.

(b) No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of Parent or Merger Sub is required in connection with the consummation by Parent or Merger Sub of the transactions contemplated by this Agreement and the Escrow Agreement except for (i) the filing of the Merger Document with the California Secretary of State; (ii) such filings as may be required under the HSR Act or any applicable state or foreign antitrust, competition, anti-takeover and similar laws; and (iii) such other consents, authorizations, filings, approvals and registrations which, if not obtained or made, would not result in and could not be reasonably expected to result in a Material Adverse Effect on Parent and would not prevent, or materially alter or delay any of the transactions contemplated by this Agreement.

4.3 Compliance with Other Instruments. The execution, delivery and performance of this Agreement by Parent and Merger Sub and the execution, delivery and performance of the Escrow Agreement by Parent will not (a) violate the charter documents or bylaws of Parent or Merger Sub, (b) breach or result in a violation of any law applicable to Parent or Merger Sub or the transactions contemplated by this Agreement or the Escrow Agreement, or (c) constitute a material breach of the terms, conditions, provisions of, or constitute a default under, any judgment, order, or decree of any court or arbitrator to which Parent or Merger Sub is a party or any material contract of Parent.

4.4 Brokers. Parent and Merger Sub have not incurred, nor will they incur, any liability for brokerage or finders' fees or agents' commissions or investment bankers' fees or any similar charges in connection with this Agreement or the consummation of the transactions contemplated hereby, other than investment bankers' fees payable to Morgan Stanley.

4.5 Financing. Attached as Schedule 4.5 is a true and correct copy of a written commitment letter from Morgan Stanley, dated February 27, 2004 (the "MS Commitment Letter"). The terms set forth in the MS Commitment Letter are satisfactory in all material respects to Parent, subject to the execution of a credit agreement with Morgan Stanley (the "MS Credit Agreement"). Upon consummation of the Debt Financing contemplated by Section 6.13, Parent will possess cash sufficient to pay the respective portions of the Closing Payment Amount it is required to pay at the Closing in accordance with the terms of this Agreement.

ARTICLE 5
CONDUCT OF BUSINESS PENDING THE MERGER AND RELATED COVENANTS

5.1 Conduct of Business of the Company. Except as expressly contemplated by this Agreement and except to the extent Parent shall otherwise consent in writing, the Company covenants and agrees that, during the period beginning on the Agreement Date and ending on the earlier of the termination of this Agreement or the Effective Time, (i) the business of the Company shall be conducted only in, and the Company shall not take any action except in the ordinary course of business and in a manner consistent with past practice or as otherwise expressly contemplated by this Agreement; (ii) the Company shall use its best efforts to preserve intact its business organization, (iii) the Company shall use commercially reasonable efforts to keep available the services of the current employees of and consultants to the Company; and (iv) the Company shall use commercially reasonable efforts to preserve the current relationships of the Company with customers, suppliers and other persons with which the Company has significant business relations. Except as expressly contemplated by this Agreement, and without limiting the foregoing, the Company shall not, directly or indirectly do, or propose to do, any of the following without the written consent of the Parent, with it being understood that each of such clauses below shall constitute an independent obligation of the Company, not qualified by any other such clause, and shall be deemed to be cumulative:

(a) Charter Documents. Cause or permit any amendments to its Restated Articles or bylaws;

(b) Dividends; Repurchases; Changes in Capital Stock. Except as otherwise specifically con-

templated in this Agreement, (i) declare or pay any dividends on, or make any other distributions (whether in cash, stock or property) in respect of, any of its capital stock, (ii) issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock, or (iii) repurchase or otherwise acquire, directly or indirectly, any shares of its capital stock (other than pursuant to repurchase rights of the Company that permit the Company to repurchase securities from the holders thereof at the original purchase price therefor in connection with the termination of services of such holder as an employee of or consultant to the Company);

(c) Stock Option Plans, Warrants, Etc. Accelerate, except with respect to grants already outstanding pursuant to the existing terms thereof or as expressly permitted by the Company Option Plan, amend or change the period of exercisability or vesting of options or other rights granted under the Company Option Plan, establish any new or additional stock option plan, amend the Company Option Plan other than to increase the number of shares reserved for issuance thereunder, or grant any options, warrants or other rights to acquire shares of Company Common Stock or Company Preferred Stock, other than options granted under the Company Option Plan;

(d) Material Contracts. Enter into any material contract or commitment, or violate, amend or otherwise modify or waive any of the terms of any agreements, understandings, instruments or contracts which are material to the business of the Company as presently conducted and as the Company currently proposes it be conducted other than (i) contracts that are entered into in the ordinary course

of business, or (ii) contracts which are terminable by the Company upon less than sixty (60) days' notice without penalty or surviving obligations. Any material contract or commitment entered into, or extended, by the Company after the Agreement Date shall provide that the consummation of the transactions contemplated by this Agreement shall not result in a breach or violation of such contract or otherwise require the payment of any fees or expenses in connection therewith, or give the other party the right to accelerate any obligations of the Company thereunder or to cause the termination of such contract.

(e) Issuance of Securities. Issue, deliver or sell or authorize or propose the issuance, delivery or sale of, or purchase or propose the purchase of, any shares of its capital stock or securities or other instruments (including notes or other evidences of Indebtedness) convertible into, or subscriptions, rights, warrants or options to acquire, or other agreements or commitments of any character obligating it to issue any such shares or other convertible instruments or securities, other than (i) shares of Company Common Stock issuable upon exercise of Company Options that are outstanding under the Company Option Plan, (ii) Company Options, or (iii) shares of Company Common Stock or Company Preferred Stock issuable upon exercise or conversion of the derivative securities listed in Section 3.2 of the Company Disclosure Schedule.

(f) Intellectual Property.

(i) Sell, license, assign or transfer any Intellectual Property of the Company to any other person other than the Parent, or encumber any Intellectual Property of the Company;

(ii) License, or otherwise acquire, any Intellectual Property not owned by the Company or the Parent from any third party on terms requiring any royalty payments or imposing other obligations on the Company; or

(iii) Cease to prosecute any current patent applications or other material Intellectual Property or fail to pay any patent or other Intellectual Property maintenance fees;

(g) Marketing or Other Rights. Except as set forth on Schedule 5.1(g) hereto, enter into or amend any agreement pursuant to which any other party is granted manufacturing, marketing or other development or distribution rights of any type or scope with respect to any of the Company's products or technology, or enter into any agreement that would limit the ability of any of the Surviving Corporation, the Parent or any Affiliate of the Parent to operate in a specific area of business or specific geographic area after the closing of the Merger.

(h) Dispositions; Obligations. Except for the sale of the Company's inventory in the ordinary course of business, sell, lease, license or otherwise dispose of or encumber any of its properties or assets which are material, individually or in the aggregate, taken as a whole, or, except for the incurrence of obligations in the ordinary course of business consistent with past practice, otherwise incur material obligations that would become obligations of the Parent upon the consummation of the Merger;

(i) Indebtedness. Incur any Indebtedness for borrowed money or guarantee any such Indebtedness or issue or sell any debt securities or guarantee any debt securities of others;

(j) Insurance. Materially reduce the amount of any material insurance coverage provided by existing insurance policies;

(k) Termination or Waiver. Terminate or waive any right of substantial value, other than in the ordinary course of business;

(l) Employee Benefit Plans; New Hires; Pay Increases. Except as set forth in Schedule 5.1(1), adopt or amend any employee benefit, pay or commit to pay any special bonuses or special remuneration to any employee or director, or, increase the salaries, bonuses or wage rates of its employees, except for increases in the ordinary course of business pursuant to periodic evaluations of employees;

(m) Severance Arrangements. Except as set forth in Schedule 5.1(m) or as otherwise explicitly contemplated by this Agreement, adopt or approve any severance, bonus or benefit acceleration arrangements (whether individually or more broadly) that could be triggered after the Agreement Date, including but not limited to after consummation of the Merger;

(n) Lawsuits. Commence a lawsuit other than (i) for the routine collection of bills, (ii) in such cases where it in good faith determines that failure to commence suit would result in the material impairment of a valuable aspect of its business, provided, that it consults with the Parent prior to the filing of such a suit, or (iii) with respect to this Agreement;

(o) Acquisitions. Acquire or agree to acquire by merging or consolidating with, or by purchasing a substantial portion of the assets of, or by any other manner, any business or any corporation, partnership, association or other business organization or division thereof which are material, individually or in the

aggregate, to the Company's business, taken as a whole;

(p) Taxes. Make or change any material election in respect of Taxes, adopt or request permission of any Taxation Authority to change any accounting method in respect of Taxes, enter into any closing agreement in respect of Taxes, settle any claim or assessment in respect of Taxes, surrender or allow to expire any right to claim a refund of Taxes, consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of Taxes, or take (or permit any Subsidiary to take) any such actions with respect to any Subsidiary;

(q) Notices. Fail to give any notices and other information required to be given to the employees of the Company, any collective bargaining unit representing any group of employees of the Company, or any applicable government authority for actions to be taken by the Company before the Closing Date under the Worker Adjustment and Retraining Act (the WARN Act), the National Labor Relations Act, the Code, the Consolidated Omnibus Reconciliation Act (COBRA), or other applicable law in connection with the transactions provided for in this Agreement;

(r) Other Transactions. Merge or consolidate with any entity other than the Parent, Merger Sub or an Affiliate of the Parent, or liquidate, dissolve or effect a recapitalization or reorganization in any form of transaction;

(s) Confidentiality Agreements. Hire, any employee or consultant having access to confidential or proprietary information of the Company unless such employee or consultant enters into, or has entered into, a proprietary information and inventions

agreement with the Company in the form of Exhibit C attached hereto or containing substantially similar confidentiality and assignment of inventions provisions, or amend or otherwise modify, or grant a waiver under, any such confidentiality or proprietary information agreement with any such person;

(t) Related Party Transactions. Enter into any transaction with any director, officer, employee, significant shareholder or family member of or consultant to any such person, corporation or other entity of which any such person beneficially owns 10% or more of the equity interests or has 10% or more of the voting power, or Subsidiary or Affiliate of the Company, except as approved by a majority of the disinterested directors of the Company Board on terms and conditions which are fair and reasonable to the Company and no less favorable to the Company as could be obtained from a third party on an arms-length basis;

(u) Principal Business. Materially participate in any business other than the Principal Business;

(v) Accounting; Accounts Receivable and Accounts Payable. Make any change in any method of accounting or accounting practice or policy other than those required by GAAP, or make any change in the Company's practices or procedures relating to collections and accounts payable or adopt any other material changes in their business policies and procedures, or manage the accounts payable of the Company other than in accordance with the Company's past practices;

(w) Other Activities. Knowingly engage in any other activity which could reasonably be expected to impair the ability of the Parent, the Merger Sub or the Company to consummate the Merger;

(x) Subsidiaries. Permit any Subsidiary of the Company to take any action from which the Company would be prohibited pursuant to this Section; or

(y) General. Authorize, commit to, agree to take, or permit to occur any of the foregoing actions.

5.2 Payment of Taxes, Etc. The Company shall, and shall cause each of its Subsidiaries to, timely file all of its material Tax Returns as they become due (taking all timely filed proper extension requests into account), all such Tax Returns to be true, correct and complete, and the Company shall, and shall cause each of its Subsidiaries to, timely pay and discharge as they become due and payable all material Taxes (other than Taxes contested in good faith by the Company or its Subsidiaries in appropriate proceedings), assessments and other governmental charges and levies imposed upon it or its income or any of its property that, if unpaid, may by law become a lien or charge upon its properties.

ARTICLE 6
ADDITIONAL AGREEMENTS

6.1 Notices; Consents; Filings. From and after the Agreement Date, the Company shall use its best efforts, at the Company's expense, to obtain the consents described in Section 3.23 of the Company Disclosure Schedule; provided, however that, without limiting the rights of Parent and Merger Sub under Section 7.2(h), the Company shall not be required to pay cash in exchange for such consents except to the extent required or contemplated by the terms of any agreement which requires such a consent. In the event that the Company shall fail to obtain any third party consent necessary for the consummation of the transactions contemplated hereby, the Shareholder Repre-

sentative shall use commercially reasonable efforts, and take any such actions reasonably requested by Parent, to minimize any adverse effect upon the Company, the Surviving Corporation and Parent, their respective Subsidiaries, and their respective businesses resulting, or which could reasonably be expected to result after the Effective Time, from the failure to obtain such consent.

6.2 HSR Act. In the event that Parent, the Company or any shareholder of Parent or the Company reasonably determines that it is required to make pre-merger notification filings (an "Antitrust Filing") under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), and any corresponding law or regulation of any foreign Governmental Authority (a "Foreign Antitrust Filing") with respect to the Merger and the other transactions contemplated hereby such party shall promptly notify each other party of such requirement and thereafter each of the parties will:

(a) as promptly as is practicable, make its required filings under the HSR Act or any laws mandating a Foreign Antitrust Filing and in connection therewith seek early termination of any applicable waiting periods thereunder;

(b) as promptly as is practicable after receiving any governmental request under the HSR Act or any corresponding law or regulation of any foreign Governmental Authority for additional information, documents, or other materials, use its commercially reasonable best efforts to comply with such request;

(c) cooperate with the other in connection with resolving any governmental inquiry or investigation, whether domestic or foreign, relating to their respec-

tive HSR Act filings, Foreign Antitrust Filings, the Merger or any related inquiry or investigation;

(d) promptly inform the other of any communication with, and any proposed understanding, agreement, or undertaking with any governmental entity, whether domestic or foreign, relating to their respective HSR Act filings, Foreign Antitrust Filings, the Merger or any related inquiry or investigation;

(e) to the extent reasonably practicable, give the other reasonable advance notice of, and the opportunity to participate in (directly or through its representatives), any meeting or conference with any governmental entity, whether domestic or foreign, relating to their respective HSR Act filings, Foreign Antitrust Filings, the Merger or any related inquiry or investigation to the extent allowed by law; and

(f) pay any filing fees required to be paid in connection with such filings, if any, under the HSR Act or in connection with any Foreign Antitrust Filings.

6.3 Further Assurances.

(a) Following the Agreement Date, each of Parent and the Company will:

(i) use its best efforts to take, or cause to be taken, all appropriate action, and to do, or cause to be done, all things necessary, proper or advisable, including such actions as may be necessary, proper or advisable under applicable laws and regulations, to consummate and make effective the Merger and the transactions contemplated hereby, including using its commercially reasonable best efforts to obtain all permits, consents, approvals, authorizations, qualifications and orders of governmental authorities as are necessary for the consummation of the Merger and the

other transactions contemplated hereby and to fulfill the conditions set forth in Article 7; and

(ii) cooperate and use its best efforts to vigorously contest and resist any action, including administrative or judicial action, and to have vacated, lifted, reversed or overturned any decree, judgment, injunction or other order (whether temporary, preliminary or permanent) that is in effect and that restricts, prevents or prohibits consummation of the Merger and the other transactions contemplated hereby, including by vigorously pursuing all available avenues of administrative and judicial appeal.

(b) In case, at any time after the Effective Time, any further action is necessary or desirable to carry out the purposes of this Agreement, the proper officers and directors of each party to this Agreement shall use their commercially reasonable best efforts to take all such action.

(c) Notwithstanding the terms of Sections 6.2 or 6.3(a), nothing in the Agreement, shall require or be construed to require any party hereto, in order to obtain the consent or successful termination of any review of any Governmental Authority regarding the transactions contemplated hereby, to (i) sell or hold separate, or agree to sell or hold separate, before or after the Effective Time, any material assets, businesses or any interests in any assets or businesses, of Parent, the Company or any of their respective affiliates (or to consent to any sale, or agreement to sell, by Parent or the Company, of any assets or businesses, or any interests in any assets or businesses), or any change in or restriction on the operation by Parent or the Company of any assets or businesses, or (ii) enter into any agreement or be bound by any obligation that, in Parent's good faith exercise of reasonable business

judgment, may have a material adverse effect on the benefits to Parent of the transactions contemplated by this Agreement. In the event that any party hereto shall be required, in order to obtain the consent or successful termination of any review under the HSR Act regarding the transactions contemplated hereby, to take any of the actions set forth in part (i) or (ii) of the preceding sentence or if such consent or successful termination has not been obtained within 90 days following the initial pre-merger notification filings of the Parent and the Company with respect to the transactions contemplated hereby have been made under the HSR Act with the U.S. Department of Justice and Federal Trade Commission (the "HSR Filing Date"), Parent shall have the right to abandon its efforts to obtain approval under the HSR Act of the transactions contemplated hereby, notwithstanding Section 6.2 or 6.3(a). In the event that consent or successful termination under the HSR Act regarding the transactions contemplated hereby has not been obtained within 120 days following the HSR Filing Date, the Company shall have the right to abandon its efforts to obtain approval under the HSR Act of the transactions contemplated hereby, notwithstanding Section 6.2 or 6.3(a). If the Parent or Company so elects to abandon its efforts to seek such approval pursuant to one of the preceding two sentences, it shall promptly give notice of such abandonment to the other party.

6.4 Shareholder Approval. As soon as practicable following the Agreement Date, the Company will promptly solicit the approval by written consent of the execution and delivery by the Company of this Agreement, and the consummation of the transactions contemplated hereby, by Company Shareholders holding the requisite number of shares of each class of

the Company's capital stock required to approve the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (the "Shareholder Approval"). Such solicitation shall be in the form of a proxy statement in a form to be mutually agreed upon by the Parent and the Company. The Company shall take all other action necessary or advisable to secure the vote or consent of shareholders required by California Law, if applicable, to obtain such approval.

6.5 Notice of Developments. Parent, on the one hand, and the Company, on the other hand, shall use reasonable efforts to give prompt written notice to the other party of any material development causing a breach of any of its own representations and warranties in this Agreement.

6.6 Exclusivity.

(a) From and after the Agreement Date until the Effective Time or termination of this Agreement pursuant to Article 8, the Company will not, nor will it authorize or permit any of its officers, directors, affiliates or employees or any investment banker, attorney or other advisor or representative retained by it to, directly or indirectly, (i) solicit, initiate or induce the making, submission or announcement of any Acquisition Proposal, (ii) participate in any discussions or negotiations regarding, or furnish to any person any non-public information with respect to, or take any other action to facilitate any inquiries or the making of any proposal that constitutes or may reasonably be expected to lead to, any Acquisition Proposal, (iii) engage in discussions with any person with respect to any Acquisition Proposal, except as to disclose the existence of these provisions, (iv) endorse or recommend any Acquisition Proposal, or (v) enter

into any letter of intent or similar document or any contract, agreement or commitment contemplating or otherwise relating to any Acquisition Proposal. The Company and its Subsidiaries will, and will cause their respective officers, directors, affiliates, employees, investment bankers, attorneys and other advisors and representatives to, immediately cease any and all existing activities, discussions or negotiations with any parties conducted heretofore with respect to any Acquisition Proposal. Without limiting the foregoing, it is understood that any violation of the restrictions set forth in the preceding two sentences by an officer or director of the Company or any of its Subsidiaries or any investment banker, attorney or other professional advisor of the Company or any of its Subsidiaries shall be deemed to be a breach of this Section 6.6 by the Company.

(b) In addition to the obligations of the Company set forth in Section 6.6(a), the Company as promptly as practicable shall advise Parent in writing of any Acquisition Proposal or of any request for nonpublic information or other inquiry which the Company reasonably believes could lead to an Acquisition Proposal, the material terms and conditions of such Acquisition Proposal (to the extent known), and the identity of the person or group making any such request, inquiry or Acquisition Proposal. The Company agrees to keep Parent informed on a current basis of the status and details (including any material amendments or proposed amendments) of any such request, inquiry or Acquisition Proposal.

6.7 Full Access. At all times from the Agreement Date until the earlier of the Effective Time or termination of this Agreement in accordance with Article 8, the Company will afford to Parent and its authorized

representatives, upon reasonable notice, full access during normal business hours to all properties, books, records, contracts and documents of the Company as Parent and such authorized representatives may reasonably request and a complete opportunity to make such investigations as Parent and such authorized representatives reasonably request, and the Company will furnish or cause to be furnished to Parent and its authorized representatives all such information with respect to the affairs and businesses of the Company as they may reasonably request to the extent allowed by law. All information obtained by Parent pursuant to this Section 6.7 shall be kept confidential in accordance with the Mutual Non-Disclosure Agreement, dated May 15, 2003 (the "Confidentiality Agreement"), between Parent and the Company. No investigation pursuant to this Section 6.7 shall affect any representation or warranty in this Agreement of any party hereto or any condition to the obligations of the parties hereto or thereto.

6.8 Certain Tax Matters. If the Company is obligated to make any payments, or is a party to any agreement that under certain circumstances could obligate it to make any payments, that will not be deductible under Section 280G of the Code if the shareholder approval requirements of Section 280G(b)(5)(B) are not satisfied and if that shareholder approval has not already been obtained, Parent agrees that it shall cooperate and assist the Company in obtaining the requisite shareholder approval described in Section 280G(b)(5)(B) of the Code, and the Company agrees that it shall use commercially reasonably efforts to obtain such shareholder approval promptly after the Agreement Date and in any event prior to the date on which the transactions contemplated by this Agreement are consummated.

6.9 Public Announcements. Prior to the closing of the Merger, the Parent shall not, without having previously informed the Company about the form, content and timing of any such announcement, issue any press release or otherwise make any public statements with respect to this Agreement or the transactions contemplated hereby, except as may be required by (a) law, (b) the SEC, (c) the Securities Act or the Exchange Act, or (d) any listing agreement with the Nasdaq National Stock Market, the National Association of Securities Dealers, Inc. or any national securities exchange to which the Parent is subject. Nothing herein express or implied shall require the Parent to consult with the Company following the closing of the Merger. The Company and the Company Shareholders shall not, without the prior written consent of the Parent, issue any press release or otherwise make any public statements with respect to this Agreement or the transactions contemplated hereby at any time.

6.10 Benefit Plans.

(a) Following the Effective Time, Parent shall arrange for each participant in the Company Benefit Plans (the "Company Participants") (including without limitation all dependents) who becomes a Parent employee (or an employee of any Parent subsidiary or Affiliate) after the Effective Time to be eligible for the same benefits in the aggregate as those received by Parent employees with similar positions and responsibilities, provided, that nothing in this Section 6.10(a) shall be deemed to require Parent to offer any particular Company Participants any particular benefit. Each Company Participant shall, to the extent permitted by law, applicable tax qualification requirements and the existing terms of the applicable

employee benefit plans, and subject to any applicable break in service or similar rule, receive credit for all purposes including, without limitation, for eligibility to participate, matching contributions, and vesting under Parent employee benefit plans for years of service with the Company (and its Subsidiaries and predecessors) prior to the Effective Time. If applicable and permitted by the relevant plan, Parent shall cause any and all pre-existing condition (or actively at work or similar) limitations, eligibility waiting periods and evidence of insurability requirements under any Parent employee benefit plans to be waived with respect to such Company Participants and their eligible dependents and shall provide them with credit for any co-payments, deductibles, and offsets (or similar payments) made during the plan year including the Effective Time for the purposes of satisfying any applicable deductible, out-of-pocket, or similar requirements under any Parent employee benefit plans in which they are eligible to participate after the Effective Time.

(b) Parent agrees that, from and after the Effective Time, the Company employees who become employees of Parent or any of its Subsidiaries or Affiliates may participate in the employee stock purchase plan sponsored by Parent (the "Parent ESPP"), subject to the terms and conditions of the Parent ESPP, and that service with the Company shall be treated as service with Parent or its Subsidiaries for determining eligibility of the Company's employees under the Parent ESPP.

6.11 Non-Competition Agreements. The Company shall use commercially reasonable best efforts to cause each of the Company's executive officers specified in Schedule 6.11 to execute and deliver a non-

competition agreement with Parent in the form attached hereto as Exhibit D-1.

6.12 Employment Agreements. The Company and Parent shall use commercially reasonable best efforts to cause the persons specified on Schedule 6.12 to enter into employment agreements in substantially the form attached hereto as Exhibit D-2. The principal terms of each such employment agreement shall be as specified on Schedule 6.12.

6.13 Debt Financing. Parent shall use its commercially reasonable best efforts to (i) negotiate, execute and deliver the MS Credit Agreement and all ancillary agreements thereto with Morgan Stanley containing terms substantially as set forth in the MS Commitment Letter and (ii) satisfy, or obtain a waiver of, all conditions applicable to Parent and within Parent's reasonable control in the MS Credit Agreement. Parent will keep the Company reasonably informed on a regular ongoing basis of the status of Parent's efforts to borrow an amount of funds at least equal to $250,000,000 pursuant to the MS Credit Agreement or otherwise (the "Debt Financing"). Notwithstanding the foregoing, nothing herein shall be interpreted to require Parent to seek to obtain the Debt Financing on terms that differ in any material respect from those set forth in the MS Commitment Letter. The Company shall provide all cooperation and assistance reasonably requested by Parent in connection with the Debt Financing.

6.14 Certain Antitrust Filings. Prior to the Closing Date or the termination of this Agreement pursuant to Section 8, Parent shall not enter into any agreement that would require Parent to file an Antitrust Filing under the HSR Act with respect any transaction contemplated by such agreement if such

Antitrust Filing would reasonably be expected to result in a material delay in the approval of or in the termination of any applicable waiting period for any Antitrust Filing filed with respect to the Merger and the other transactions contemplated by this Agreement.

6.15 Tail Insurance Coverage. The Company shall elect to purchase the "tail" or "extension" with a duration of at least five years under the product liability and general liability insurance policies in effect as of the Agreement Date and listed in Section 3.19 of the Company Disclosure Schedule to the extent permitted in accordance with the terms thereof.

ARTICLE 7
CONDITIONS TO THE MERGER

7.1 Conditions to the Obligations of Each Party. The obligations of the Company, Parent and Merger Sub to consummate the Merger are subject to the satisfaction of each of the following conditions:

(a) no order, stay, decree, judgment or injunction shall have been entered, issued or enforced by any court of competent jurisdiction which prohibits consummation of the Merger, and there shall not be any action taken by any Governmental Authority, or any statute, rule, regulation or order enacted, entered, enforced or deemed applicable to the Merger, which makes the consummation of the Merger illegal or substantially deprives Parent, the Company or the Participating Rights Holders of any of the anticipated benefits of the Merger or the related transactions, taken as a whole;

(b) all actions by or in respect of or filings with any Governmental Authority required to permit the consummation of the Merger in accordance with the

terms hereof, including but not limited to the expiration or early termination of the waiting period under the HSR Act, shall have been obtained (other than those actions or filings which, if not obtained or made prior to the consummation of the Merger, would not result in and could not be reasonably expected to result in a Material Adverse Effect on the Company prior to or after the Effective Time or a Material Adverse Effect on Parent after the Effective Time or be reasonably likely to subject the Company, Parent, Merger Sub, or any of their respective Subsidiaries or any of their respective officers or directors to substantial penalties or criminal liability); and

(c) the Shareholder Approval shall have been obtained.

7.2 Conditions to the Obligations of Parent and Merger Sub. The obligations of Parent and Merger Sub to consummate the Merger are subject to the satisfaction of the following further conditions (any one of which may be waived in whole or part by Parent in its sole discretion by giving written notice to the Company in compliance with Section 10.1 hereof):

(a) (i) the Company shall have performed all of its material obligations hereunder required to be performed by it at or prior to the Effective Time; and (ii) Parent shall have received a certificate dated as of the Closing Date and signed by the Company's President or Chief Executive Officer, certifying to the foregoing effect;

(b) (i) each of the representations and warranties of the Company contained in this Agreement shall have been true and correct (without regard to any qualifications to such representations and warranties as to materiality, Material Adverse Effect

of similar expressions) at the time originally made (as qualified by the Company Disclosure Schedule) and the representations and warranties made as of the Agreement Date shall be true and correct as of the Effective Time (as qualified by the Company Disclosure Schedule delivered on the Agreement Date), except for breaches of such representations and warranties that, individually or in the aggregate, would not and could not reasonably be expected to result in a Material Adverse Effect; and (ii) the Company shall deliver to Parent at the Closing a certificate, dated as of the date of the Closing and signed by the Company's President or Chief Executive Officer, certifying to that effect;

(c) no Material Adverse Effect with respect to the Company shall have occurred or been discovered by Parent since the Agreement Date;

(d) no injunction or other decree shall have been issued by any court of competent jurisdiction prohibiting the sale of the Company Products by the Company or Parent on the basis of any rights held by a third party (including without limitation any rights of any third party in any. Intellectual Property);

(e) Wilson Sonsini Goodrich & Rosati will have issued a legal opinion addressed to Parent in the form attached hereto as Exhibit E;

(f) the Company shall have delivered a properly executed statement, dated as of the Closing Date, in a form reasonably acceptable to Parent conforming to the requirements of Treasury Regulation Section 1.1445-2(c)(3);

(g) the Company shall have delivered to Parent and Merger Sub a certificate that sets forth (i) the information required to be set forth on Section 3.2

of the Company Disclosure Schedule, updated to reflect capitalization as of immediately prior to the Effective Time (giving effect to any conversion of shares of Company Preferred Stock to Company Common Stock that is made contingent upon the Closing), (ii) the Fully-Diluted Common Stock Number and the calculation thereof, and (iii) the aggregate exercise price for all Company Options and Company Warrants outstanding as of the Agreement Date (the "Capitalization Certificate"), which Capitalization Certificate shall be deemed to be representations and warranties of the Company hereunder;

(h) the Company shall have obtained those consents or approvals with respect to the consummation of the Merger of each person listed on Schedule 7.2(h);

(i) any and all rights, warrants, options or other instruments or rights to purchase shares of Company Common Stock or Company Preferred Stock (other than Company Options and Company Warrants, which shall be converted into the right to receive a portion of the Closing Payment Amount in accordance with Section 2.1) outstanding immediately prior to the Closing, whether or not exercisable, whether or not vested, and whether or not performance based, shall have been exercised or terminated

(j) holders of no more than 5.0% of the aggregate outstanding Company Common Stock and Company Preferred Stock (calculated on an as-converted to Company Common Stock basis) as of the Effective Time shall have elected to, or continue to have contingent rights to, exercise dissenters', appraisal or similar rights under California Law with respect to such shares; and

(k) the Company shall have delivered a certification to Parent, in form and substance (other than with respect to any amounts set forth thereon) satisfactory to Parent, setting forth the maximum amount of fees and expenses that each professional advisor engaged by the Company or its Board of Directors in connection with this Agreement or the Company's efforts to consummate an initial public offering of the Company Common Stock, consisting of Piper Jaffray, Wilson Sonsini Goodrich & Rosati and Ernst & Young, will charge with respect to the transactions contemplated hereby or the Company's efforts to consummate an initial public offering of the Company Common Stock (regardless of whether or not such fees and expenses have been billed to, or collected from, the Company) (each a "Transaction Cost Certificate"), and Parent shall have received such written assurances with respect to such amounts from Piper Jaffray and Wilson Sonsini Goodrich & Rosati as it shall reasonably request; and

(l) each holder of Company Warrants shall have executed and delivered a amendment, in form and substance reasonably satisfactory to Parent, to the Company Warrants held by such holder acknowledging such holder will receive the portion of the Closing Payment Amount calculated pursuant Section 2.1(c)(ii) in exchange for such Company Warrants; or, alternatively, for any holders who have not delivered such amendment, the Company Warrants held by such holders shall terminate no later than the Effective Time.

7.3 Conditions to the Obligations of the Company. The obligations of the Company to consummate the Merger are subject to the satisfaction of the following

further conditions (any one of which may be waived in whole or part by the Company):

(a) (i) Parent and Merger Sub shall have performed all of their respective material obligations hereunder required to be performed by them at or prior to the Effective Time; and (ii) the Company shall have received a certificate from each of Parent and Merger Sub, each signed by an executive officer of Parent or Merger Sub, as appropriate, to the foregoing effect;

(b) (i) each of the representations and warranties of the Parent and the Merger Sub contained in this Agreement shall have been true and correct at the time originally made (as qualified by the Parent Disclosure Schedule) and the representations and warranties made as of the Agreement Date shall be true and correct as of the Effective Time (as qualified by the Parent Disclosure Schedule delivered on the Agreement Date), except for breaches of such representations and warranties that, individually or in the aggregate, would not and could not reasonably be expected to result in a Material Adverse Effect; and (ii) the Company shall have received a certificate from each of Parent and Merger Sub, each signed by an executive officer of Parent or Merger Sub, as appropriate, certifying to that effect;

(c) no Material Adverse Effect with respect to the Parent shall have occurred or been discovered by Company since the Agreement Date which could reasonably be expected to result in the Parent being unable to consummate the Merger in accordance with the terms hereof on or before the Final Termination Date; and

(d) Bingham McCutchen LLP will have issued a legal opinion in the form attached hereto as Exhibit F.

ARTICLE 8
TERMINATION.

8.1 Termination. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time, notwithstanding any requisite approval and adoption of this Agreement and the transactions contemplated hereby by the Company Shareholders:

(a) by duly authorized mutual written consent executed by each of Parent, Merger Sub and the Company;

(b) by the Company if the Parent has not consummated the Debt Financing, or otherwise obtained cash in an amount sufficient to pay the aggregate amount payable in respect of the Merger at the Closing, on or before the later of the 30th day following the Agreement Date or the fifth (5th) business day following the date on which the conditions under Sections 7.1 and 7.2(a)(i), (b)(i), (c), (d), (h) and (j) have been satisfied and the Company has certified to the Parent that it could, as of such date, deliver each certificate or other document required from the Company by Sections 7.2(a)(ii), (b)(ii), (f), (g) and (k) (or in the case of Section 7.2(e), that Wilson Sonsini Goodrich & Rosati could deliver the document required by such section) (the "Company Financing Termination Date"), provided, that the right to terminate this Agreement under this Section 8.1(b) shall not be available to the Company if it is not exercised by the Company prior to the end of the day

on the fifth business day following the Financing Termination Date.

(c) by Parent, if the Parent has not consummated the Debt Financing, or otherwise obtained cash in an amount sufficient to pay the aggregate amount payable in respect of the Merger at the Closing, on or before the 30th day following the Agreement Date (the "Parent Financing Termination Date"), provided, that the right to terminate this Agreement under this Section 8.1(b) shall not be available to Parent unless the Debt Financing shall not have been consummated prior to the Financing Termination Date because Morgan Stanley shall have elected not to enter into the MS Credit Agreement or otherwise not consummate the Debt Financing as a result of either of the events described in clauses (b), (c) (as it relates to the Company only), and (d) of the last paragraph of page 2 of the MS Commitment Letter or any similar provision in the MS Credit Agreement.

(d) by Parent, or by the Company, if the Effective Time shall not have occurred before the 90th day following the Agreement Date (the "Final Termination Date"); provided, however, that (i) in the event that one or both of Parent and the Company (or any shareholder thereof) are required or deem it advisable to make an Antitrust Filing under the HSR Act, or under similar foreign statutes or regulations, or seek any other governmental approvals or authorizations as may be reasonably necessary in connection with the closing of the Merger, including any filings or notifications as may be reasonably necessary that are to be made under California Law, the Final Termination Date shall be delayed, without further action of the parties, until the tenth (10th) business day after, with respect to each necessary

approval or authorization, (x) the date on which any applicable waiting periods thereunder have expired or been terminated so that such approval or authorization is no longer required or (y) the date on which the necessary approval and authorization is received, as applicable and (ii) the right to terminate this Agreement under this Section 8.1(d) shall not be available to Parent in the event that the failure of the Effective Time to occur on or before such date arises out of or is related to Parent's failure to fulfill any obligation under this Agreement and the right to terminate this Agreement under this Section 8.1(d) shall not be available to the Company in the event that the failure of the Effective Time to occur on or before such date arises out of or is related to the failure by the Company to fulfill any obligation under this Agreement;

(e) automatically if there shall be any law that makes consummation of the Merger illegal or otherwise prohibited or if any court of competent jurisdiction or Governmental Authority shall have issued an order, decree, ruling or taken any other action restraining, enjoining or otherwise prohibiting the Merger and such order, decree, ruling or other action shall have become final and non-appealable;

(f) by Parent, by giving written notice to the Company at any time prior to the Closing in the event that the Company has given Parent any notice pursuant to Section 6.5 above, if the breach or breaches described in such notice would, individually or in the aggregate, render any condition to the Merger contained in Sections 7.1 or 7.2 hereof impossible of being satisfied;

(g) by the Company, by giving written notice to Parent at any time prior to the Closing in the event

that Parent has given the Company any notice pursuant to Section 6.5 above, if the breach or breaches described in such notice would, individually or in the aggregate, render any condition to the Merger contained in Sections 7.1 or 7.3 hereof impossible of being satisfied; or

(h) automatically, in the event that Parent or Company delivers notice of abandonment of its efforts under the HSR Act in accordance with Section 6.3(c).

8.2 Effect of Termination. Except as provided in Section 8.1 hereof, in the event of the termination of this Agreement pursuant to Section 8.1, this Agreement shall forthwith become void, there shall be no liability under this Agreement on the part of Parent, Merger Sub or the Company or any of their respective officers, directors, or shareholders, and all rights and obligations of any party hereto shall cease, except for liabilities arising from a breach of this Agreement prior to such termination.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Parent and the Surviving Corporation.

(a) Subject to the limitations set forth in Section 9.5 hereof, from and after the Effective Time, Parent and the Surviving Corporation, jointly and severally, will indemnify, defend and hold harmless each of the Company Shareholders, the Participating Rights Holders and each of their respective directors, officers, employees, representatives and other Affiliates (each such Indemnified Person a "Rights Holder Indemnitee"), from and against any and all Damages related to or arising out of or in connection with any breach by Parent or Merger Sub of any representation,

warranty, covenant, agreement, obligation, or undertaking made by Parent or Merger Sub in this Agreement (including any schedule or exhibit hereto), or any other agreement, instrument, certificate or other document delivered by or on behalf of Parent or Merger Sub in connection with this Agreement, the Merger, or any of the other transactions contemplated hereby.

(b) At all times after the Effective Time, each Company Shareholder and Participating Rights Holder shall be entitled to rely as third-party beneficiaries on the mutual promises of Parent and Merger Sub pursuant to this Agreement and the Escrow Agreement.

9.2 Indemnification of Parent by Resort to Escrow. Subject to the limitations set forth in Section 9.5 hereof, from and after the Effective Time, Parent, the Surviving Corporation, and each of their respective directors, officers, employees, representatives and other Affiliates (each such Indemnified Person a "Parent Indemnitee") shall be entitled to recover from the Escrowed Funds any and all Damages suffered by such Parent Indemnitee related to or arising out of or in connection with:

(a) any breach by the Company of any representation, warranty, covenant, agreement, obligation or undertaking made by such party in or pursuant to this Agreement, or any other agreement, instrument, certificate or other document delivered by or on behalf of the Company in connection with this Agreement, the Merger, or any of the other transactions contemplated hereby, including but not limited to the Capitalization Certificate;

(b) any actual liability of the Company, the Surviving Corporation or any of its Affiliates for death

or injury to person or property related to or arising out of the complaints described in Schedule 9.2(b) hereto only to the extent such Damages are not covered by insurance obtained by the Company prior to the Effective Time (collectively, "Product Liability Claims");

(c) any payments made by Parent, the Merger Sub or the Surviving Corporation after the Effective Time with respect to any Dissenting Shares to the extent that such payments exceed the portion of the Closing Payment Amount to which the holders of such Dissenting Shares would have been entitled had such Dissenting Shares not been Dissenting Shares, with any claims made pursuant to this Section 9.2(c) being referred to hereafter as the "Appraisal Claims";

(d) any lawsuit filed before the first anniversary of the Closing Date asserting claims or allegations that the development, manufacture, marketing, distribution or sale of the Company Products infringes or violates any patent rights or patents of third parties (collectively "Specified Intellectual Property Claims"); or

(e) any amounts which the Parent is required to pay in respect of fees, expenses and other costs incurred in respect of professional advisors engaged by the Company in connection with this Agreement and the transactions contemplated hereby, or the Company's efforts to consummate an initial public offering of the Company Common Stock (including any fees and expenses of legal counsel, outside auditors and financial advisors retained by the Company or its Board of Directors); but only to the extent that such costs and expenses exceed the aggregate total of the maximum amounts specified in the Transaction Cost Certificate (such aggregate total being the "Aggregate

Maximum Transaction Cost" and such claims collectively constituting the "Transaction Cost Claims").

9.3 Third-Party Claims.

(a) In the event that any Rights Holder Indemnitee desires to make a claim against an Indemnifying Party (which term shall be deemed to include all Indemnifying Parties if more than one) or in the event that any Parent Indemnitee desires to make a claim against the Escrowed Funds in connection with any third-party litigation, arbitration, action, suit, proceeding, claim or demand at any time instituted against or made upon it for which it may seek indemnification hereunder (a "Third-Party Claim"), the Indemnified Person will promptly notify the Indemnification Control Person of such Third-Party Claim and of its claims of indemnification with respect thereto; provided, that failure to promptly give such notice will not relieve the Indemnifying Party of its indemnification obligations under this Section 9.3, except to the extent, if any, that the person or persons represented by the Indemnification Control Person have actually been prejudiced thereby.

(b) The Indemnification Control Person will have the right to assume the defense of the Third-Party Claim with counsel of its choice reasonably satisfactory to the Indemnified Person by written notice to the Indemnified Person within twenty (20) days after the Indemnification Control Person has received notice of the Third-Party Claim; provided, however, that the Indemnification Control Person must conduct the defense of the Third-Party Claim actively and diligently thereafter in order to preserve the rights of the person or persons represented by the Indemnification Control Person in this regard; and provided, further, that the Indemnified Person may

retain separate co-counsel at its sole cost and expense and participate in the defense of the Third-Party Claim.

(c) The Indemnification Control Person will not consent to the entry of any judgment or enter into any settlement with respect to the Third-Party Claim without the prior written consent of the Indemnified Person (which consent will not be unreasonably conditioned, withheld or delayed) unless the judgment or proposed settlement (i) includes an unconditional release of all liability of each Indemnified Person with respect to such Third-Party Claim, and (ii) involves only the payment of money damages that are fully covered by the Indemnifying Party (or fully covered by amounts paid pursuant to Section 9.4 by distribution of amounts to Parent Indemnitees from Escrowed Funds) and does not impose an injunction or other equitable relief upon the Indemnified Person. So long as the Indemnification Control Person has assumed and is conducting the defense of the Third-Party Claim in accordance with Section 9.3(b) above, the Indemnified Person will not consent to the entry of any judgment or enter into any settlement with respect to the Third-Party Claim without the prior written consent of the Indemnification Control Person (which consent will not be unreasonably conditioned, withheld or delayed).

(d) In the event that the Indemnification Control Person fails to assume the defense of the Third-Party Claim in accordance with Section 9.3(b) above, (i) the Indemnified Person may defend against, and consent to the entry of any judgment or enter in to any settlement with respect to, the Third-Party Claim in any manner it reasonably may deem appropriate (and the Indemnified Person need not consult

with, or obtain any consent from, the Indemnification Control Person in connection therewith), and (ii) the Indemnifying Party will remain responsible (or, as applicable, the Parent Indemnitee may claim and recover from the Escrowed Funds) for any Damages the Indemnified Person may suffer as a result of such Third-Party Claim to the extent subject to indemnification under this Article 9.

(e) Notwithstanding the foregoing, Parent and the Surviving Corporation shall be responsible for the prosecution and defense of any claims relating to the Intellectual Property of the Company (collectively, the "Parent-Handled Claims"). Parent and the Surviving Corporation shall pursue in good faith, through counsel of their selection, the prosecution or defense of all Parent-Handled Claims until such time, if any, that Parent shall elect not to pursue indemnification with respect to such Third-Party Claim.

(f) Parent shall, to the extent that Parent and the Surviving Corporation are entitled to indemnification for Damages pursuant to this Article 9 and it could reasonably be expected that Parent may recover a substantial portion of the Damages relating to such Parent-Handled Claim pursuant to this Article 9, (i) provide the Shareholder Representative with access to appropriate employees of Parent and the Surviving Corporation for the purpose of discussing matters relating to Parent-Handled Claims as the Shareholder Representative may from time to time reasonably request, (ii) permit the Shareholder Representative, upon its reasonable request, to participate in the process of any settlement or other resolution of any Parent-Handled Claims pursuant to this Article 9; and (iii) secure the written consent of the Shareholder Representative before settling any Parent-Handled

Claim (which consent shall not be unreasonably withheld, delayed or conditioned).

9.4 Payment of Claims. In the event of any bona fide claim for indemnification hereunder, the Indemnified Person will advise the Indemnification Control Person in writing, advising the Indemnification Control person of the amount of the claim and, with reasonable specificity, the circumstances surrounding the claim. With respect to liquidated claims for Damages, if within thirty (30) days the Indemnification Control Person has neither objected nor contested to such claim in writing, the Indemnifying Party will pay the full amount thereof (or in the case of a claim by an Parent Indemnitee against the Escrowed Funds, such Parent Indemnitee shall recover the full amount thereof from the Escrowed Funds), subject to the limitations set forth in Section 9.5. If the Indemnification Control Person objects to such claim in writing within such thirty-day period, the objection will be resolved pursuant to the procedures in the Escrow Agreement. All recoveries from Escrowed Funds shall be made on a *pro rata* basis from the amounts that would otherwise be released from the Escrowed Funds to the Participating Rights Holders. The parties agree that to the greatest extent possible the payment of any indemnity hereunder shall be treated as an adjustment to the Closing Payment Amount paid by Parent hereunder for Tax purposes. Indemnification obligations of Parent and the Merger Sub shall be satisfied by the Parent in cash. Except in the case of fraud, resort to indemnification pursuant to this Article 9 through claims against the Escrowed Funds shall be the sole remedy of Parent and Merger Sub and any other Parent Indemnitee with respect to any and all Damages related to or arising out of or in connection with

(i) any breach by Company of any representation, warranty, covenant, agreement, obligation or undertaking made by the Company in or pursuant to this Agreement or any other agreement, instrument, certificate or other document delivered by or on behalf of the Company in connection with this Agreement, or (ii) any other claim, for indemnification or otherwise, arising out of or related to the subject matter of this Agreement or any other agreement, instrument, certificate or other document delivered by or on behalf of the Company in connection with this Agreement.

9.5 Limitations of Liability.

(a) Deductible. No Indemnifying Party will be required to indemnify an Indemnified Person and no claim may be made against the Escrowed Funds hereunder until such time as the amount of Damages for which (i) all Parent lndemnitees, on the one hand, or (ii) all Rights Holder Indemnitees, on the other hand, are otherwise entitled to indemnification pursuant to this Agreement exceeds $500,000 in the aggregate for all such Damages, and then only to the extent such aggregate amount exceeds $500,000. No Indemnifying Party will be required to indemnify any Rights Holder Indemnitee hereunder with respect to any claim for Damages unless the amount of Damages for which all Rights Holder Indemnitees are entitled for such claim exceeds $50,000 in the aggregate. No claim may be made against Escrowed Funds by any Parent Indemnitee unless the amount of Damages for which all Parent Indemnitees are entitled from such claim exceeds $50,000 in the aggregate. Notwithstanding anything to the contrary in this Section 9.5, the minimum claim limit and deductible imposed by this Section 9.5(a) shall not apply to any Damages arising out of or in connection with (A) any breach by the

Company of any Special Representations, (B) any Special Claims, or (C) fraud, nor shall any such Damages be counted against the foregoing deductible.

(b) Maximum Recovery.

(i) The parties specifically agree that, notwithstanding any provision of this Agreement to the contrary, the maximum aggregate recovery by all Parent Indemnitees from the Escrowed Funds for indemnification under this Article 9, except in the case of fraud, will not exceed a maximum amount equal to the amount of the Initial Escrow Amount originally deposited into escrow pursuant to the Escrow Agreement. The parties specifically agree that, notwithstanding any provision of this Agreement to the contrary, the maximum recovery of all Rights Holder Indemnitees from the Parent under this Article 9, except in the case of fraud, will not exceed a maximum amount equal to the amount of the Initial Escrow Amount originally deposited into escrow pursuant to the Escrow Agreement.

(ii) As a further limitation, any claims of Parent Indemnitees against the Escrowed Funds for indemnification under this Article 9 with respect to Specified Intellectual Property Claims shall not exceed $10,000,000 in the aggregate for all such Specified Intellectual Property Claims (the "Specified Intellectual Property Claims Cap"), and as a further limitation, shall not exceed $7,000,000 with respect to Specified Intellectual Property Claims related to any single third party (taken together with all of its affiliates and related persons and entities) (the "Specified Intellectual Property Claims Per Claim Cap"). Notwithstanding the foregoing, the Specified Intellectual Property Claims Cap shall be reduced to $7,000,000, until such time (if ever) before the first

anniversary of the Closing Date that a third party specified on Schedule 9.2(d) hereto files a lawsuit that results in a Specified Intellectual Property Claim; after such a claim is filed (if ever), the Specified Intellectual Property Claims Cap shall be increased to $10,000,000, however, the Specified Intellectual Property Claims Per Claim Cap will remain at $7,000,000.

(iii) As a further limitation, with respect to any Product Liability Claims, Parent and the Surviving Corporation must use commercially reasonable efforts to seek reimbursement from applicable insurance policies and first apply insurance proceeds from applicable insurance policies to any Damages related to Product Liability Claims; thereafter, once such insurance proceeds, if any, are exhausted, any Parent Indemnitee may make a claim against the Escrowed Funds for Damages related to Product Liability Claims; provided, however that Parent Indemnitees shall not be entitled to recover an amount with respect to such claims in excess of $5,000,000 in the aggregate (the "Product Liability Claims Cap"). Notwithstanding the foregoing, unless an insurance carrier has paid the Product Liability Claims to the extent of insurance coverage limits or confirmed in writing that it will cover the Known Claims to the extent of insurance coverage limits, without reservations other than customary limited exclusions that do not reference specific facts or circumstances that the applicable carrier has identified as a potential basis for the denial of coverage, after making claims for indemnification that would exceed the Product Liability Claims Cap, any Parent Indemnitee may make a further claim against the Escrowed Funds for Damages related to any Product Liability Claim not defended by an insurance carrier; provided, however that such claims

shall be limited to a portion of the Escrowed Funds (distinct from and in addition to the Product Liability Claims Cap portion) not to exceed an additional $5,000,000 in the aggregate, less any amounts that have been paid by insurance in respect of Product Liability Claims (the "Supplemental Product Liability Claims Cap"). For avoidance of doubt, the purpose of the Supplemental Product Liability Claims Cap portion of the Escrowed Funds is to provide a remedy for the Parent if the Company's existing insurance carriers determine pursuant to applicable insurance policies not to cover the Product Liability Claims to the extent of insurance coverage limits, and it is the intent of the parties that such Supplemental Product Liability Claims Cap will not be available to Parent if insurance coverage for Product Liability Claims is available.

(c) Time Limit. All representations and warranties in this Agreement shall survive the Closing and shall expire on, and no Indemnifying Party will be liable for any Damages hereunder and no claim may be made against the Escrowed Funds with respect to a breach of such representations and warranties unless a written claim for indemnification is given by the Indemnified Person to the Indemnification Control Person with respect thereto prior to, the first anniversary of the Closing Date (the "Claim Deadline"). The right to make claims for indemnification, shall expire as of the Claim Deadline, except with respect to claims (i) that have been duly noticed before Claim Deadline and (ii) for which a reserve from the Escrowed Funds has been duly established, each of (i) and (ii) in accordance with this Agreement and the Escrow Agreement, as applicable, provided, that notwithstanding the foregoing, the right of Parent to make claims for indemnification with respect to a Product

Liability Claim shall survive until the sixtieth (60th) day following the final resolution, including but not limited to by way of final settlement agreement of all of the parties or issuance of an order of a court having jurisdiction over the matter which is final and not subject to further court proceedings or appeal, of the matter underlying such Product Liability Claim.

(d) No Liability of Company Shareholders, Participating Rights Holders or Shareholder Representative. Notwithstanding anything to the contrary in this Agreement and for purposes of clarification, except in the case of fraud, the liability of the Participating Rights Holders, including indemnification obligations, under this Agreement shall be limited to the Escrowed Funds; and, once amounts held pursuant to the Escrow Agreement are released to the Participating Rights Holders pursuant to the terms of the Escrow Agreement, Parent, the Surviving Corporation and any Affiliates thereof and any other Parent Indemnitees shall have no further claim to the amount thereof from the Participating Rights Holders, except in the case of fraud. Without limiting the ability of the Parent to recover from the Escrowed Funds in accordance with this Article 9, and except in the case of fraud, nothing in this Agreement shall cause the Shareholder Representative or Participating Rights Holders to become personally liable for any indemnification claim pursuant to the provisions of this Article 9.

9.6 Right to Bring Action; No Contribution. Notwithstanding anything in this Article 9 or elsewhere in this Agreement to the contrary, only the Shareholder Representative shall have the right, power and authority to commence any action, suit or proceeding, including any arbitration proceeding, by

and on behalf of any or all Participating Rights Holders against Parent or the Surviving Corporation or any other Indemnified Person in connection with the Agreement and the Escrow Agreement and the transactions contemplated herebyand thereby, and in no event shall any Participating Rights Holder himself, herself or itself have the right to commence any action, suit or proceeding, including any arbitration proceeding, against Parent or the Surviving Corporation, or any other Indemnified Person in such connection. By virtue of the adoption of this Agreement and the approval of the Merger by the Company Shareholders, each Participating Rights Holder (regardless of whether or not such Participating Rights Holder votes in favor of the adoption of the Agreement and the approval of the Merger, whether at a meeting or by written consent in lieu thereof) shall be deemed to have waived, and shall be deemed to have acknowledged and agreed that such Participating Rights Holder shall not have and shall not exercise or assert (or attempt to exercise or assert), any right of contribution, right of indemnity or other right or remedy against Surviving Corporation in connection with any indemnification obligation or any other liability to which he may become subject under or in connection with this Agreement.

ARTICLE 10

GENERAL PROVISIONS

10.1 Notices. All notices, claims and demands hereunder, and all other communications which are required to be given in writing pursuant to this Agreement, shall be in writing and shall be given (and shall be deemed to have been duly given upon receipt) by delivery in person or facsimile (received at the facsimile machine to which it is transmitted prior

to 5 p.m., local time, on a business day for the party to which it is sent, or if received after 5 p.m., local time, as of the next business day) or by registered or certified mail (postage prepaid, return receipt requested) to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 10.1):

if to Parent or Merger Sub:

Cytyc Corporation
85 Swanson Road
Boxborough, MA 01719
Attention: Vice President — Corporate Development
Facsimile: (978) 266-3008

with a copy to:

Bingham McCutchen LLP
150 Federal Street
Boston, Massachusetts 02110
Attention: Johan V. Brigham, Esq.
Facsimile: (617) 951-8736

if to the Company:

Novacept, Inc.
1047 Elwell Court
Palo Alto, California 94303 Attention: President
Facsimile: (650) 335-2613

with a copy to:

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Christopher D. Mitchell, Esq.
Facsimile: (650)-493-6811

and if to the Shareholder Representative:

David Clapper
860 Hobart Street
Menlo Park, CA 94025
Facsimile: (650)-493-6811 (c/o Chris Mitchell)

and:

Edward Unkart
6 Valley Oak
Portola Valley, CA 94028
Facsimile: (650)-493-6811 (c/o Chris Mitchell)

with a copy to:

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Christopher D. Mitchell, Esq.
Facsimile: (650) 493-6811

10.2 Certain Definitions. For purposes of this Agreement, the term:

"Acquisition Proposal" means any bona fide offer or proposal (other than an offer or proposal by Parent) relating to any Acquisition Transaction.

"Acquisition Transaction" means (a) any transaction or series of related transactions other than the transactions contemplated by this Agreement involving the purchase of all or any significant portion of the capital stock or assets of the Company, (b) any agreement to enter into a business combination with the Company, (c) any agreement made, other than in the ordinary course of business, with regard to the Intellectual Property owned or licensed by the Company, and (d) any other extraordinary business transaction involving or otherwise relating to the Company or any Intellectual Property owned or licensed by the Company.

"Affiliate" means, with respect to any person, any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such person. Until the consummation of the Merger, the Company shall not be deemed for any purposes of this Agreement to be an Affiliate of the Parent.

"Closing Payment Amount" means the amount of (i) $325,000,000, plus (ii) the aggregate exercise price of all Company Options and Company Warrants outstanding and unexercised immediately prior to the Effective Time; and minus (iii) the Aggregate Maximum Transaction Cost.

"Code" means the Internal Revenue Code of 1986, as amended.

"Company Licensed Intellectual Property" means all Intellectual Property licensed to the Company or any of its Subsidiaries by any third party.

"Company Owned Intellectual Property" means all Intellectual Property owned by the Company or any of its Subsidiaries.

"Company Products" means the Company's NovaSure impedance controlled endometrial ablation system in its current configuration, together with all enhancements thereto currently under development.

"Company Warrant" means each unexercised right, warrant or option to purchase Company Common Stock or Company Preferred Stock listed in Section 3.2(f) of the Company Disclosure Schedule or the Capitalization Certificate.

"Conversion Rate", with respect to any series of Company Preferred Stock, means at any point in time the number of shares of Company Common Stock into

which each share of such Company Preferred Stock may be converted pursuant to the then effective Restated Articles.

"Damages" means all damages, losses, costs, and expenses incurred or suffered, or that are reasonably likely to be incurred or suffered, by a party with respect to or relating to an event, circumstance or state of facts. Damages shall specifically include court costs and the reasonable fees and expenses of legal counsel arising out of or relating to any direct or third-party claims, demands, actions, causes of action, suits, litigations, arbitrations or liabilities.

"Environmental Law" means any judgment, decree, order, law license, rule or regulation pertaining to environmental matters, including those arising under any federal, state or local statute, regulation, ordinance, order or decree relating to the environment or exposure to a Hazardous Substance.

"Environmental Permit" means all material permits, licenses and other authorizations required under any Environmental Law.

"Escrowed Funds" means the amounts delivered to the Escrow Agent pursuant to the provisions of Section 1.5 hereof less any such amounts distributed to the Participating Rights Holders or to any Parent Indemnitee by the Escrow Agent in accordance with this Agreement or the Escrow Agreement.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"FDA" means the United States Food and Drug Administration.

"Financial Statements" means (a) the audited consolidated financial statements (including balance

sheet, income statement and statement of cash flows) as of and for the year ended December 31, 2003, and with respect to representations made as of the Closing Date also means (b) the unaudited consolidated financial statements (including balance sheet, income statement and statement of cash flows) as of the end of the most recently completed fiscal quarter prior to the Closing Date, and for the portion of the current fiscal year ended on such date, each of which the Company has made available to the Parent or its counsel and included in the Company Disclosure Schedule.

"Fully-Diluted Common Stock Number" means (i) the number of shares of Company Common Stock outstanding immediately prior to the Effective Time (including Dissenting Shares and any shares of Company Stock that would be issued upon conversion of any shares of Company Preferred Stock that have elected to be, or are required to be, converted into Company Common Stock as of immediately prior to the Effective Time in connection with the Merger), plus (ii) the maximum number of shares of Company Common Stock issuable upon exercise of unexercised Company Options and Company Warrants outstanding immediately prior to the Effective Time, and minus (iii) any shares of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants (all calculated similarly as above) held by the Company or any Subsidiary of the Company or by Parent or any Affiliate of Parent. For the purposes of this calculation, the number of shares of Company Common Stock issuable upon exercise of any Company Warrants exercisable for Company Preferred Stock shall be deemed to be such number of shares of Company Preferred Stock multiplied by the

conversion ratio for the applicable series of Company Preferred Stock.

"GAAP" means United States generally accepted accounting principles consistently applied.

"Governmental Authority" (whether such term is capitalized or not) means any United States (federal, state or local) or foreign government, or governmental, regulatory or administrative authority, agency or commission.

"Hazardous Substance" means (a) those substances defined in or regulated under the following federal statutes and their state counterparts and all regulations thereunder: the Hazardous Materials Transportation Act, the Resource Conservation and Recovery Act, the Comprehensive Environmental Response, Compensation and Liability Act, the Clean Water Act, the Safe Drinking Water Act, the Atomic Energy Act, the Federal Insecticide, Fungicide, and Rodenticide Act and the Clean Air Act; (b) petroleum and petroleum products, including crude oil and any fractions thereof; (c) natural gas, synthetic gas, and any mixtures thereof; (d) polychlorinated biphenyls, asbestos and radon; and (e) any substance, material or waste regulated by any federal, state, local or foreign Governmental Authority pursuant to any Environmental Laws.

"Indebtedness" means, as applied to any person, (a) all indebtedness for borrowed money, whether current or funded, or secured or unsecured, (b) all indebtedness for the deferred purchase price of property or services represented by a note or other security, (c) all indebtedness created or arising under any conditional sale or other title retention agreement with respect to property acquired (even though the

rights and remedies of the seller or lender under such agreement in the event of default are limited to repossession or sale of such property), (d) all indebtedness secured by a purchase money mortgage or other lien to secure all or part of the purchase price of property subject to such mortgage or lien, (e) all obligations under leases which shall have been or must be, in accordance with GAAP, recorded as capital leases in respect of which such person is liable as lessee, (f) any liability in respect of banker's acceptances or letters of credit, and (g) all indebtedness referred to in clauses (a), (b), (c), (d), (e) or (f) above which is directly or indirectly guaranteed by or which such person has agreed (contingently or otherwise) to purchase or otherwise acquire or in respect of which it has otherwise assured a creditor against loss.

"Indemnification Control Person" means (i) in the event of a claim by a Rights Holder Indemnitee, the Parent or (ii) in the event of a claim made by a Parent Indemnitee against the Escrowed Funds, the Shareholder Representative.

"Indemnifying Party" means any person against whom indemnification may be sought pursuant to the provisions of Article 9.

"Indemnified Person" means any person entitled to seek indemnification pursuant to the provisions of Article 9.

"Intellectual Property" means intellectual property or proprietary rights of any description including (a) rights in any patent, patent application (including any provisionals, continuations, divisions, continuations-in-part, extensions, renewals, reissues, revivals and reexaminations, any national phase PCT applications,

any PCT international applications, and all foreign counterparts), copyright, industrial design, URL, domain name, trademark, service mark, logo, trade dress or trade name, (b) related registrations and applications for registration, (c) trade secrets, moral rights or publicity rights, and (d) inventions, discoveries, or improvements, modification, know-how, technique, methodology, writing, work of authorship, design or data, whether or not patented, patentable, copyrightable or reduced to practice, including any inventions, discoveries, improvements, modification, know-how, technique, methodology, writing, work of authorship, design or data embodied or disclosed in any: (i) computer source code (human-readable format) and object code (machine-readable format); (ii) specifications; (iii) manufacturing, assembly, test, installation, service and inspection instructions and procedures; (iv) engineering, programming, service and maintenance notes and logs; (v) technical, operating and service and maintenance manuals and data; (vi) hardware reference manuals; and (vii) user documentation, help files or training materials.

"knowledge" of the Company or any Subsidiary whether or not capitalized means the actual knowledge of David Clapper, Edward Unkart, Russ Sampson, Eugene Skalnyi and Donald Nathe.

"Material Adverse Effect" means with respect to the Company or Parent, as the case may be, any change or effect that, when taken individually or together with all other adverse changes or effects, materially adversely effects the business, results of operations and financial condition of the Company or Parent, as the case may be, together with their respective Subsidiaries, taken as a whole; provided, however that any event or occurrence resulting from the announce-

ment or pendency of the Merger, this Agreement and the transactions contemplated hereby shall not be deemed to result in a Material Adverse Effect; provided, further, however that any event or occurrence resulting from (i) changes in general economic or political conditions, (ii) changes in law, regulation or policy or (iii) changes in the healthcare industry generally, the medical device industry generally or the market for products and procedures for the treatment of excessive menstrual bleeding in particular shall not be deemed to result in a Material Adverse Effect, unless in any such instance such change described in (i), (ii) or (iii) above impacts the Company in a materially disproportionate manner relative to a preponderance of other entities impacted by such change.

"PBGC" means the Pension Benefit Guaranty Corporation.

"Participating Rights Holders" means those persons (other than the holders of Dissenting Shares, the Company, Parent or any Subsidiary of the Company or Parent) who, immediately prior to the Effective Time of the Merger, were holders of shares of Company Common Stock, Company Preferred Stock, Company Options or Company Warrants and whose interests therein, as the result of the Merger, are converted into rights to receive a portion of the Closing Payment Amount.

"Per Share Common Closing Payment" means the amount equal to the quotient obtained by dividing (x) the amount of the Closing Payment Amount minus the Preferred Closing Payment Amount, and minus the Representative Reimbursement Amount, by (y) the Fully-Diluted Common Stock Number.

"Per Share Preferred Closing Payment" means, with respect to each share of any series of Company Preferred Stock outstanding immediately prior to the Effective Time (other than any shares of Company Preferred Stock held by Parent and any shares of Company Preferred Stock converted into Common Stock immediately prior to the Effective Time in connection with the Merger), the portion of the Closing Payment Amount allocable to such share, in preference to any share of Company Common Stock or other series of Preferred Stock, pursuant to the Company's Restated Articles as in effect immediately prior to the Effective Time.

"Preferred Closing Payment Amount" means an amount equal to the sum of all Per Share Preferred Closing Payments for all series of Company Preferred Stock.

"Principal Business" means the design, development, manufacture, marketing and sale of the Company Products.

"Restated Articles" means the Amended and Restated Articles of Incorporation of the Company.

"SEC" means the United States Securities and Exchange Commission.

"Securities" means all shares of Company Common Stock and Company Preferred Stock, all outstanding options, warrants, convertible notes, rights of conversion and other rights to acquire capital stock of the Company, and all shares issuable upon exercise or conversion of the Company Preferred Stock, options, warrants, convertible notes, rights of conversion and other rights to acquire stock of the Company, outstanding from time to time, whether or not then currently vested, exercisable or convertible.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Securityholder" means any holder of Securities.

"Shareholder Representative" means the individual appointed to serve as such under Section 2.5.

"Special Claims" means any Tax Claims, Appraisal Claims, Product Liability Claims and Transaction Cost Claims.

"Special Representations" means any representations or warranties relating to Section 3.2 of this Agreement or representations or warranties contained in the Capitalization Certificate.

"Subsidiary or Subsidiaries" (whether or not capitalized) of any person means any corporation, partnership, limited liability company, association, trust, joint venture or other legal entity of which such person (either above or through or together with any other Subsidiary), owns, directly or indirectly, more than 50% of the stock or other equity interests the holders of which are generally entitled to vote for the election of the board of directors or other governing body of such corporation or other legal entity.

"Tax" or "Taxes" (and with correlative meaning, "Taxable" and "Taxing") means any United States federal, state or local, or non-United States, income, gross receipts, franchise, estimated, alternative minimum, add-on minimum, sales, use, transfer, registration, value added, excise, natural resources, severance, stamp, withholding, occupation, premium, windfall profit, environmental, customs, duties, real property, personal property, capital stock, net worth, intangibles, social security, unemployment, disability,

payroll, license, employee or other tax or similar levy, of any kind whatsoever, including any interest, penalties or additions to tax in respect of the foregoing.

"Taxation Authority" means any Governmental Authority having any responsibility for (a) the determination, assessment or collection or payment of any Tax, or (b) the administration, implementation or enforcement of or compliance with any law relating to any Tax.

"Tax Claims" means a claim resulting from any breach of any representation or warranty in Section 3.24 of this Agreement or any covenant in Sections 5.1(p), 5.2, or 6.8 of this Agreement;

"Tax Return" means any return, declaration, report, claim for refund, information return or other document (including any related or supporting estimates, elections, schedules, statements or information) filed or required to be filed in connection with the determination, assessment or collection of any Tax or the administration of any laws, regulations or administrative requirements relating to any Tax.

The following table sets forth certain other defined terms and the Section of the Agreement in which the meaning of each such term appears:

	Section(s)
"Activities to Date"	3.21(a)
"Agreement"	Preamble
"Aggregate Maximum Transaction Cost"	9.2(e)
"Agreement Date"	Preamble
"Antitrust Filing"	6.2
"Appraisal Claims"	9.2(c)

	Section(s)
"California Law"	Preamble
"Capitalization Certificate"	7.2(i)
"Certificates"	2.2(a)(i)
"Claim Deadline"	9.5(c)
"Closing"	1.1(b)
"Closing Date"	1.1(b)
"Company"	Preamble
"Company Board"	Preamble
"Company Common Stock"-	Preamble
"Company Disclosure Schedule"	Article 3
"Company Financing Termination Date"	8.1(b)
"Company Licenses"	3.21(a)
"Company Option"	2.1(c)
"Company Option Plan"	2.1(c)
"Company Participants"	6.10(a)
"Company Preferred Stock"	Preamble
"Company Shareholders"	Preamble
"Company Warrant"	2.1(c)(ii)
"Confidentiality Agreement"	6.7
"Debt Financing"	6.13
"Derivative Instruments"	2.2(a)(i)
"Dissenting Shares"	2.4(a)
"Effective Time"	1.1(b)
"Employee Benefit Plan"	3.20(a)

	Section(s)
"Escrow Agent"	1.5(b)
"Escrow Agreement"	1.5(b)
"Final Termination Date"	8.1(d)
"Foreign Antitrust Filing"	6.2
"HIPPA"	3.14
"HSR Act"	6.2
"HSR Filing Date"	6.3(c)
"Initial Escrow Amount"	1.5(b)
"Joint Representative"	2.5(a)
"Merger"	Preamble
"Merger Document"	1.1(b)
"Merger Sub"	Preamble
"MS Commitment Letter"	4.5
"MS Credit Agreement"	4.5
"Notified Party"	3.9(g)
"Option Shares"	2.1(c)
"Parent"	Preamble
"Parent ESPP"	6.10(b)
"Parent Financing Termination Date"	8.1(c)
"Parent-Handled Claims"	9.3(e)
"Parent Indemnitee"	9.2
"Permits"	3.14
"Product Liability Claims"	9.2(b)
"Product Liablity Claims Cap"	9.5(b)(iii)

	Section(s)
"Recent Tax Returns"	3.24(a)
"Representative Reimbursement Amount"	1.5(c)
"Rights Holder Indenmitee"	9.1(a)
"Shareholder Approval"	6.4
"Specified Intellectual Property Claims"	9.2(d)
"Specified Intellectual Property Claims Cap"	9.5(b)(ii)
"Specified Intellectual Property Claims Per Claim Cap"	9.5(b)(ii)
"SR Expenses"	2.5(c)
"Surviving Corporation"	1.1
"Surviving Corporation Charter"	1.3(a)
"Third-Party Claim"	9.3(a)
"Transaction Cost Certificate"	7.2(k)
"Transaction Cost Claims"	9.2(e)
"Warrant Shares"	2.1(c)(ii)

10.3 Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of applicable law, or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the Merger is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that

the Merger be consummated as originally contemplated to the fullest extent possible.

10.4 Entire Agreement; Assignment. This Agreement, together with the Confidentiality Agreement and, when executed and delivered by the parties thereto, the Escrow Agreement, constitutes the entire agreement among the parties with respect to the subject matter hereof and thereof and supersedes all prior agreements and undertakings, both written and oral, among the parties, or any of them, with respect to the subject matter hereof and thereof. This Agreement shall not be assigned by operation of law or otherwise, except that (a) Parent and Merger Sub may assign all or any of their rights and obligations hereunder to any Affiliate of Parent; provided, that no such assignment to an Affiliate shall relieve the assigning party of its obligations hereunder, and (b) after the Effective Time, Parent may assign all of its rights and obligations hereunder to a person that acquires all of the capital stock, or substantially all of the assets, of the division or business unit of Parent responsible for the business of the Company; provided, that such person assumes this Agreement, in writing, and agrees to be bound by and to comply with all of the terms and conditions hereof.

10.5 Parties in Interest. This Agreement shall be binding upon and inure solely to the benefit of each party hereto and nothing in this Agreement, express or implied is intended to or shall confer upon any other person any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.6 Specific Performance. The parties hereto agree that irreparable damage would occur in the event that any provision of this Agreement was not performed in accordance with the terms hereof and

that the parties shall be entitled to specific performance of the terms hereof, in addition to any other remedy at law or equity.

10.7 Governing Law. This Agreement shall be governed by, and construed in accordance with the laws of the State of California applicable to contracts executed in and to be performed in that state.

10.8 Consent to Jurisdiction.

(a) EACH OF PARENT, THE COMPANY AND MERGER SUB HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE COURTS OF CALIFORNIA AND TO THE JURISDICTION OF THE UNITED STATES DISTRICT COURT FOR NORTHERN DISTRICT OF CALIFORNIA, FOR THE PURPOSE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND EACH OF PARENT, THE COMPANY AND MERGER SUB HEREBY IRREVOCABLY AGREES THAT ALL CLAIMS IN RESPECT TO SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED EXCLUSIVELY IN ANY CALIFORNIA STATE OR FEDERAL COURT SITTING IN THE CITY OF SAN FRANCISCO. EACH OF PARENT, THE COMPANY AND MERGER SUB AGREES THAT A FINAL JUDGMENT IN ANY ACTION OR, PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY LAW.

(b) EACH OF PARENT, THE COMPANY AND MERGER SUB IRREVOCABLY CONSENTS TO THE SERVICE OF THE SUMMONS AND COMPLAINT AND ANY OTHER PROCESS IN ANY

OTHER ACTION OR PROCEEDING RELATING TO THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, ON BEHALF OF ITSELF OR ITS PROPERTY, BY THE PERSONAL DELIVERY OF COPIES OF SUCH PROCESS TO SUCH PARTY. NOTHING IN THIS SECTION 10.8 SHALL AFFECT THE RIGHT OF ANY PARTY TO SERVE LEGAL PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

10.9 Headings; Interpretation. The descriptive headings contained in this Agreement are included for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the word "include," "includes," or "including" appears in this Agreement, it shall be deemed in each instance to be followed by the words "without limitation."

10.10 Counterparts. This Agreement may be executed and delivered (including by facsimile transmission) in one or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

10.11 Fees and Expenses. Except for claims for Damages pursuant to Article 9 and as provided in Section 2.5(c) hereof and as such fees and expenses are incorporated in the definitions of "Closing Payment Amount" and "Aggregate Maximum Transaction Cost", each party hereto shall be responsible for all fees and expenses (including the fees and expenses of legal counsel and financial advisors engaged by such parties) incurred by such party in connection with the preparation and negotiation of this Agreement, and the consummation of the transactions contemplated

hereby, including, in the case of the Company, any fees and expenses incurred by the Company in any related or alternative transactions, including but not limited to the preparation and filing of the Company's registration statement on Form S-1 filed with the SEC on January 12, 2004 and any amendments thereto.

10.12 Amendment. This Agreement may be amended prior to the Effective Time only by an instrument in writing, duly authorized by the Company Board, executed by Parent or its designee, the Merger Sub, the Company and the Shareholder Representative. This Agreement may be amended subsequent to the Effective Time only by an instrument in writing executed by Parent, the Surviving Corporation and the Shareholder Representative, after authorization by written consent the Participating Rights Holders entitled to a majority in amount of the Escrowed Funds then in the possession of the Escrow Agent.

10.13 Waiver. At any time prior to the Effective Time, Parent and the Company may agree to (a) extend the time for the performance of any obligation or other act of the other (including, in the case of Parent, the Merger Sub) party hereto, (b) waive any inaccuracy in the representations and warranties of the other contained herein or in any document delivered pursuant hereto, and (c) waive compliance by the other, as the case may be, with any agreement or condition contained herein. Any such extension or waiver shall be valid if set forth in an instrument in writing signed by the party or parties to be bound thereby.

* * *

[The remainder of the page is intentionally left blank.]

* * *

IN WITNESS WHEREOF, Parent, Merger Sub, the Company and, for the limited purposes of agreeing to perform the duties specified in Section 2.5, the Shareholder Representative, have duly executed this Agreement and Plan of Merger as an instrument under seal as of the date first above written.

CYTYC CORPORATION

By: /s/ Patrick J. Sullivan
Name: Patrick J. Sullivan
Title: President

RADIO ACQUISITION CORP.

By: /s/ Patrick J. Sullivan
Name: Patrick J. Sullivan
Title: President

NOVACEPT

By: /s/ David M. Clapper
Name: David Clapper
Title: President

SHAREHOLDER REPRESENTATIVE

for the limited purposes of agreeing to perform the duties expressly delegated to the "Shareholder Representative" hereunder

/s/ David M. Clapper
Name: David Clapper, Joint Representative

/s/ Edward Unkart
Name: Edward Unkart, Joint Representative

From: mare@minervasurgical.com
Sent: Sunday, July 18, 2010 5:42 PM
To: Michael Regan
Subject: Fw: Resend: Questions for budget purposes regarding endometrialablation trials

Mike

Interesting. We're getting better response from FDA than from our own advisory board.

Talk to you tomorrow.

Mary

Sent via BlackBerry by AT&T

From: "Pollard, Cohn M." <Collin.Pollard@fda.hhs.gov> Date: Sun, 18 Jul 2010 16:57:22 -0700
To: Mary Edwards<marye@minervasurgical.com>
Subject: RE: Resend: Questions for budget purposes regarding endometrial ablation trials

I'm sorry. I was away last week on vacation. I had hoped my last e-mail to you would help, but I will find some time to talk to you tomorrow, even if it's late in the day.

Colin

From: Mary Edwards [mailto:marye@minervasurgical.com]
Sent: Monday, July 12, 2010 7:51 PM
To: Pollard, Colin M.
Subject: RE: Resend: Questions for budget purposes regarding endometrial ablation trials

Colin:

I'm under huge fire because I warvs not able to get answers after almost 6 weeks. [I know it's crazy for you; but not getting any internal sympathy]. We have a board meeting on the 20th and fundraising will be dependent on the regulatory plan. I'm really hoping that we could touch base for just a couple minutes on the Monday when you return. I fully understand that some of the below might sound new — but they really are not new questions.

1. We are still going to use resection/rollerball as the control arm.
2. We are not changing any of the other endpoints hence the non-inferiority margin of 20%.
3. The Minerva device is almost dead identical to NovaSure except using plasma energy (RF).
4. The 6 months question is straight out of the guidance document which states PMA can be filed with 6 months data. I thought that had changed to filing the PMA with full 12 month data, but just needed to confirm.
5. There was rumors in the investment community that because of the switch to AH instead of PBLAC that the patient numbers have gone up (rumor has it at approximately 600 patients).

6. Lastly, you had committed to me for some feedback regarding the number of follow-ups for AH. (all I need is whether it will be 3,6 and 12 or 3 and 6— plus baseline, of course).

From: Thomas Pendlebury
To: Dave Clapper; Eugene Skalnyi; Jon Wangsness; Michael Regan; Dominique Filloux
Sent: 8/15/2015 4:27:31 PM
Subject: FW: JMIG article about Minerva endometrial ablation
Attachments: ATT00001.htm: JMIG Article.pdf

Dave, Eugene,

This (his e-mail below) is from Dr. Tom Fromuth, Lancaster, PA. I will be talking with him next week to get details on # cases and date.

Tom

Dr. Deborah Willwerth named CEO at Heart of Lancaster

By Larry Portzline, (February 23, 2013 at 11:07 AM

Dr. Deborah Willwerth has been named chief executive officer of Heart of Lancaster Regional Medical Center, according to a news release from the hospital today.

Dr. Deborah Willwerth
Dr. Deborah Willwerth - (Photo/Submitted)

From: Thomas Fromuth <tfromie@comcast.net>
Date: Friday, August 14, 2015 at 7:24 AM
To: Deborah Willwerth <deborah.Willwerth@hma.com>
Subject: Fwd: JMIG article about Minerva endometrial ablation

Deborah,

Attached is the article about Minerva, the newest endometrial ablation technique to be FDA approved. It is based on the technology of Novasure, the most

common type of ablation procedure we do at Heart. It augments the technology to improve the overall effectiveness and amenorrhea rate while maintaining the same safety profile. I would really like for Heart to be the first in the area to use this newest technology. As I mentioned it is a new start up company so will not be a member of the CHS purchasing group.

I have tried over the last few months to work through our system to get it in at least for a trial. I have had no success; not sure why. Please help me to get some of the devices purchased at least as a trial. I have the support of many of my physicians who also would like to try it. If you approve of and can help with getting the devices I can ask the surgery desk to put several ablations on one day with as many physicians as we can. The inventor of the device has offered to come in and train all of us. I worked with him in the past when he developed the Novasure and together we brought Novasure to Lancaster.

I appreciate in advance anything you can do to help Thank you.

drtomfromuth

Begin forwarded message:

From: Thomas Pendlebury <thomas.pendlebury@minervasurgical.com>
Subject: JMIG article
Date: August 12, 2015 at 10:16:44 AM EDT
To: Thomas Fromuth <tfromie@comcast.net>

From: Csaba Truckai
To: Callahan, Amanda
CC: Csaba Truckai
Sent: 12/19/2014 10:51:07 AM
Subject: RE: Patent declaration

Dear Mandy:

Following up on my email sent December 2, 2014 reference to US Patent Application No. 13/003,011, I have now reviewed the Declaration that you attached to your letter of November 21, 2014, and I cannot in good faith sign it. The Declaration states that "I believe that I am the original inventor or an original joint inventor of a claimed invention in the application." I have reviewed the claims in the application that you provided, and I do not believe that those claims define any invention. The use of mechanical spreaders for indicating the width of a uterus was well known at the time that we tiled the application describing uterine measurement. I was aware of such devices, and I incorporated such features into the device design described in the application that you sent. At no time have I ever considered the use of the mechanical indicator mechanism disclosed and for the first time now claimed in the application to be an invention.

Thus, I cannot sign the Declaration. Best regards,

Csaba Truckai

-----Original Message-----

From: Callahan, Amanda
[mailto:Amanda.Callahan@hologic.com]
Sent: Monday, December 03, 2014 2:12 PM
To: Csaba Truckai
Subject: RE: Patent declaration

Good evening Csaba – thanks very much for getting back to me so quickly. Next week is perfect; safe journeys home!

All the best, Mandy

Mandy Callahan
IP Paralegal
O: 503-263-3492
F: 50M-263-2959
Amanda.Callahan@hologic.com

Hologic, Inc. 250 Campus Drive
Marlborough, MA 01752

-----Original Message-----

From: Csaba Truckai
[mailto:csabat@hermesinnovations.com]
Sent: Tuesday, December 02, 2014 2:34 PM
To: Callahan, Amanda
Subject: Patent declaration

Dear Amanda,

I am in Europe till late next week (pending Lufthansa strike). My wife told me that I need to sign the declaration for a patent. I hope next week is not to late for returning the document.

Best,

Csaba

Sent from my iPhone

Inadequate physician training and inexperience related to Minerva Device use has the potential to lead to use error. Although you specify in your label that physicians using the Minerva Endometrial Ablation System should have sufficient training in performing hysteroscopic procedures and be familiar with the Operator's Manual, including the trouble shooting section, experience with one device type does not necessarily translate into mastery with another. In order to optimize patient safety and new provider use, please clarify whether you have implemented any specific training practices when introducing your product to physician groups for initial clinical use.

Since the start of Minerva Endometrial Ablation System commercialization the Minerva Surgical has not developed and/or implemented any specific training practices when introducing our product to physician groups for initial clinical use. In large this was and continues to be based on the fact that adequacy of Physician Training with any device and mastery of any surgical procedure is fundamentally controlled, monitored and verified by the Credentialing Departments of each medical institution/facility. They operate using their own Standards and methods in assessing the degree of such adequacy and overall proficiency. Pre-requisites and requirements used by different institution vary and we are not aware of mechanisms for credentialing of such "industry sponsored training" modules.

Most importantly, endometrial ablation in general and independently of the method used is not novel and quite uniform with respect to patient selection criteria. When it comes to the steps of Minerva procedure, it is important to appreciate that the Minerva system was specifically designed to virtually mimic the steps of the NovaSure procedure, endometrial ablation procedure

most commonly used in the United States today. As a result, during our almost 16 months of commercialization we observed a seamless transition from NovaSure and adoption of Minerva.

Lastly, we would like to state that Minerva Surgical as a company never received requests for formal training from medical institutions and/or individual physicians.

Outlook E-mail

From: O'Neill, Tom
Sent: 8/18/2015 7:20:56 AN
To: Parachek, Whitney; GSS Division Sales Management Team
Cc: GSS Division Sales RBD Team; Mascari, Adam; Hunter, Mark; Sharma, Val; Sheffer, Danielle; Compton, Eric; McMahon, Bob
Subject: RE: Minerva Hiring

Team,

Great message by both Whit and Brian!

While you don't know me yet, I have past experience in a "star- up" company. The best thing we can do is to not let them get a footing in ANY market. This will put tremendous financial pressure on their entire organization and we will stop them in there tracks. Their entire company/business model is set up to eventually sell to a PE or to a strategic. In short, Minerva is all about driving to a sale of the company. WE on the other hand are in it for the long term. We are focused on long term commitment to our customers and to women's health long term.

I have also heard from some of you that they are hiring some of ex Hologic reps who are very good. While I don't know these individuals, I do know that you as a collective group are closing an amazing year. You have 12+ year old products and you are growing near double digits this past quarter. To that end, they may have some very good ex Hologic reps hut the CLEAR FACT IS THAT YOU ARE BETTER!

Take it personally. Don't let them off the ground. Don't let them have even one case. We will win as a team!

Tom

From: Parachek, Whitney
Sent: Friday, August 14, 2015 6:50 AM
To: GSS Division Sales Management Team
Cc: GSS Division Sales RBD Team; Mascari, Adam; Hunter, Mark; O'Neill, Tom; Sharma, Vai; Sheffer, Danielle
Subject: Re: Minerva Hiring

This is fantastic guidance and leadership from Brian! It's specific, actionable, and in complete alignment with the strategies we've discussed. Please read and replicate this message to your teams TODAY. We need ALL hands on deck to insulate our business, isolate this distraction, and demonstrate our story of

commitment and partnership to our customers. .

His analogy of "ankle biting vs. hemorrhaging" is right on! We may lose a case but we will not lose an account. TMs must understand their priority NS accounts and have a plan in place to defend them. As a management team, we need to be inspecting our position in these accounts and exploring options to lock down our business.

This is our call to action! These next 3 months are critical! We cannot allow them any traction. With over 200 people sharing our value messagee will not be beat! Thank you, Brian!

Game On!
Whitney

Sent from my iPhone

CA TEAM –

As you can see from Dan's email below Minerva is ramping up their sales force with a sales training class taking place this week and In September.

As discussed on our call I want each of you to work with a sense of urgency and belief that you will have a new competitor in your territory tomorrow. As we invest in our clinical competitive knowledge let's make sure upfront you know those "Beachhead" accounts you can't afford to allow any access whatsoever. The goal is to drive your competition to those inconsequential accounts where case conversion/ankle biting is not going to lead to absolute hemorrhaging of your business. I have attached a MS Infiltration report that is sorted by stack ranking of NS sales. I have highlighted in green each of your top accounts. The top forty accounts of this list comprise of approximately 64% of our Novasure sales in the past four quarters. My expectation is that you similarly know and have a plan for those top accounts that drive the majority of your NS sales. We need to defend and prepare to wage war in these accounts. Think of your defense of these accounts as building a moat around your castle. The more successful we are upfront of this defense the better positioned we are to execute on the year we all expect to have in 2016. Think "#1 District in the Country" and "COE".

So how do we execute from an activity perspective in these key accounts today:

- Sell the whole HOI.X story / value proposition
- Maximize the TM/CS partnership
- Senior Management account visit
- DrivelT promotion

- Leverage our entire product portfolio
- Implement multi product agreements with market share commitments
- Ramp up frequency and reach of calls to the key practices and physicians that are the volume driver of these key acounts...(you can be sure the competitor will be knocking on these doors)
- Quality clinical calls to the entire office...MD, APC, Biller, Surgery Scheduler
- Raise the level of visibility of the great solutions that NS is by painting the office with NS marketing collateral....at a minimum patient education (English & Spanish) and poster clings
- Consultative approach... engage your customers / practices on how you can assist to grow their procedures
- Via a Business review help them understand the reimbursement picture / what their plans reimburse / leverage the economic calculator
- Super User Dinners // APC & Surgery Scheduler Dinners
- Leverage your territory physician advocates

The first 90-180 days are going to be absolutely critical in keeping the competition at bay. Our best opportunity at denying them the ability to capture attention and Initiate trials Is going to be right out of the gate. As busy as we are with Myosure...competing for new accounts, securing contractual commitments and selling MS/AQcapital we can't lose sight of how important the work upfront is to defend the Novasure business we have developed over the past 10 plus years. TM's please take a look at your Novasure stack ranking and

email me back by the close of business Wednesday, Aug 195h with your top five accounts and the total amount of sales each had over the last four successive quarters. We will be discussing these accounts and the key physicians that drive the volume in the corning weeks.

Thanks,

Brian Logan | District Sales Manager, California District
Mobile: 559-244-9305 | brian.logan@hologic.com
Hologic, Inc. | 250 Campus Drive, Marlborough, MA 01752

<image001.jpg>

From: Eby, Daniel
Sent: Wednesday, August 12, 2015 7:04 AM
To: Logan, Brian
Cc: Surg Mgrs West Region
Subject: Re: Minerva hires

Team

Thanks for the updates here. There is a new hire training taking place this week, so they will be in the field next. There is another training taking place place 9/16.

They are going to be active and coming after our business. Let's be sure to keep communication high in these areas where they are being placed.

Thanks-

Dan Eby
616-450-5792

<Top NS Customers.xls>
<image001.jpg>

Outlook E-mail

From: O'Neill, Tom
Sent: 10/2/2015 8:46:36 AM
To: Parachek, Whitney; Fruhan, Bill; Evantash, Edward
Subject: RE: Minerva

Thank you. Let's plan on reviewing the plan and the costs by next Friday. Does that work?

From: Parachek, Whitney
Sent: Friday, October02, 2015 7:57 AM
To: O'Neill, Tom; Fruhan, Bill; Evantash, Edward
Subject: RE: Minerva

Tom,

Sorry for the delayed response. I planned to respond to this during our 1:1 but we did not get to it.

We have an outline of aggressive ideas for a "scorched earth" strategy that I will forward. These will he vetted and prioritized with the Minerva Task Force later this afternoon. I met with Adam Jay this week and clarified his priorities in his interiMinerva defense" role. He will be attending the Task Force meeting and will work closely with me and the team to outline next steps.

Edward, Bill, and I met to discuss expediting Regional education/training summits and are outlining the roll out. Our goal is to pilot our first program in early December in California and estimate the cost to be @ $90,000. We'e also engaged Anne to discuss a "turn key" office strategy to include social selling and co-op marketing to implement with our customers to drive partnership, growth and insulation. We strongly believe med/ed (both large and small programs) and marketing

will be our key to solidifying our message, our customers, and our business.

Once vetted and prioritized we will present to you recommended strategies and budgets.

Thanks,
Whitney

From: O'Neill, Tom
Sent: Wednesday, September 30, 2015 9:32 AM
To: Fruhan, Bill; Evantash, Edward; Parachek, Whitney
Subject: Minerva

Where are we with the Minerva defense program we discussed last week at dinner?

Thanks, Tom

Strategy Planning Meeting Key Themes and Take Aways

NovaSure key issues:

1. Lost market share
2. IP expiring in 2016
3. Key competitors entering GEA market in 2015
4. Quality complaints are up considerably

NovaSure Sales Flattening- ANALYZE AND DEPLOY PROPER SIZE AND SKILL SALESFORCE

- DTC appears to be having a positive effect in the marketplace.
- Economy, more specifically patient deductibles, have stopped the short term growth of the GEA market. (Can we help pay deductibles????)
- Effect of DTC also muted by some declining share. Share loss due to both competitive ramping up of sales and GSP decreased time per product with launch of MyoSure.
- The contraindication is hurting. Rather than our reps using it to leverage Adiana we have been outsold. If we are contraindicated for use with Essure so should every other thermal energy product. I would like to see a study launched immediately to show the thermal effects of other products used in conjunction with the Essure coil. This should be combined with an analysis of the MAUDE database.
- Marketing to launch a customer satisfaction survey
- Marketing to launch patient pathway survey- where are we losing them these days and why

- Brodeur to provide the public with information about robotic complications and costs

NovaSure Gen 4- ACCELERATE OUR TIME TO MARKET

- AEGEA and Minerva are for real and they aren't going to just go away. They are well capitalized with very viable product platforms.
- We can buy them before they get through clinicals
  - Pros- Could become next generation NS
  - Cons- Likely expensive and where does it stop
- R&D/BD subcommittee to determine strategy here
- Current thinking on Gen 4: Smaller diameter catheter. This is right thought process but not enough. NovaSure is successful because it is quick, simple, safe, successful. We need to focus on more quick and more simple. Workflow and patient comfort key concepts.
- We are out of time and need to solve this problem. We have been working on feasibility for a year and our concept is not complete.
- Our Gen 4 team must focus their efforts on laying minefields around our products to:
  - A. Prevent more entrants into this field
  - B. Protect our current portfolio
- What Gen 4 isn't- A rush to copy the small features of a new entrant that will simply move to a price strategy in the event they offer no new features. We need to "move the cheese" and we need to move it quickly. While we are inventing the next smartphone we also need to invent an IPAD.

Adiana key issues:

1. Regulatory hurdles on RO and 2.0
2. Patency rates
3. 2015 revenue decreased massively due to efficacy labeling
4. Instant occlusion is the holy grail

Concomitant Use: NEW PRE-IDE REQUEST FOR THIS CHANGED PROTOCOL

- Current $6M strategy costly, too long, and not aggressive enough. Sales/Marketing says it will help- need to quantify how much. How do we avoid class labeling change?
- Attempt to eliminate the HSG requirement- can fall back to current clinical if this path fails.

2.0- CHANGE ACCESS STUDY PROTOCOL IN ANTICIPATION OF FDA REQUEST FOR CLINICAL?

- It is now possible that the 2.0 catheter will need some form of clinical beyond the access study. Potential cost for delay is $24M+ lost business.
- Need regulatory/Marketing/R&D caucus and decision on this
- Requirements should be issued to team for IP submissions. We must focus on protecting our edge here

APACS

- Delay tied to RO. Continue enrolling dots.

RO

- Not yet understood how RO will affect the patency rate. Initial in-growth data appears positive.

Sales

- Remains a complicated sale with excess sales time spent on getting people back after a negative event (expectation setting???)

MyoSure Key Issues

1. Patent Suit
2. Definition of polyp device
3. Office reimbursement strategy (why?)

- Work around for lawsuit is now #1 priority
- Speed to market of a polyp device can be accomplished with a hybrid ATEC/MyoSure product. We don't have to invent the IPAD here. COGS= $70.
- We are nowhere on the polyp device and haven't determined what it is yet. We need a PDD ASAP so we can get started on designing this product. Nicole to complete.
- Is it worth bringing this device into the office? Will it be supported? Where will this market be in 3 years? Where will our reps be? Can we get reimbursement increased here?

THS Key Issues

1. Transfer price very high- sales commitment high as well
2. 2012 less of an office focus

- We are selling these products and not just placing them. This needs to add revenue and cash to the GSP income statement.
- Need to incorporate into rep comp to see any focus from sales force.

General themes/comments

- We are spending too much time in the office (I'm not sure I agree with this- smaller territories may fix this)
- We have a negative reputation- especially regarding price flexibility
- Strength of new hires (Hunter/Farmer)

Tactical notes

- Key account development (more Mayo's)
- Heightened presence in residency programs
- We must focus our tactical or the message becomes diluted with the reps

Doc code: Oath
Document Description: Oath or declaration filed

PTO/AIA/02 (07-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)

Title of Invention	MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

This statement is directed to:

☐ The attached application,

OR

☒ United States application or PCT international application number 13/962,178 filed on August 8, 2013.

LEGAL NAME of inventor to whom this substitute statement applies:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Csaba Truckai

Residence (except for a deceased or legally incapacitated inventor):

City	State	Country
Saratoga	CA	US

Mailing Address (except for a deceased or legally incapacitated inventor):

19566 Arden Court

City	State	Zip	Country
Saratoga	CA	95070	US

I believe the above-named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this statement is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Relationship to the inventor to whom this substitute statement applies:

- ☐ Legal Representative (for deceased or legally incapacitated inventor only),
- ☒ Assignee,
- ☐ Person to whom the inventor is under an obligation to assign,
- ☐ Person who otherwise shows a sufficient proprietary interest in the matter (petition under 37 CFR 1.46 is required), or
- ☐ Joint Inventor.

PTO/SB/AIA02 (07-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SUBSTITUTE STATEMENT

Circumstances permitting execution of this substitute statement:

- ☐ Inventor is deceased,
- ☐ Inventor is under legal incapacity,
- ☐ Inventor cannot be found or reached after diligent effort, or
- ■ Inventor has refused to execute the oath or declaration under 37 CFR 1.63.

If there are joint inventors, please check the appropriate box below:

- ■ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) naming the entire inventive entity has been or is currently submitted.

OR

- ☐ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) has not been submitted. Thus, a Substitute Statement Supplemental Sheet (PTO/AIA/11 or equivalent) naming the entire inventive entity and providing inventor information is attached. See 37 CFR 1.64(b).

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

Name: Lindsay G. McGuinness | Date (Optional): 4/21/2015

Signature: Lindsay G McGuinness

APPLICANT NAME AND TITLE OF PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

If the applicant is a juristic entity, list the applicant name and the title of the signer:

Applicant Name: Cytyc Surgical Products

Title of Person Executing This Substitute Statement: VP, Deputy General Counsel & Chief IP Counsel

The signer, whose title is supplied above, is authorized to act on behalf of the applicant.

Residence of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent):

City Marlborough | State MA | Country US

Mailing Address of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent)

250 Campus Drive

City Marlborough | State MA | Zip 01752 | Country US

Note: Use an additional PTO/AIA/02 form for each inventor who is deceased, legally incapacitated, cannot be found or reached after diligent effort, or has refused to execute the oath or declaration under 37 CFR 1.63.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Thermal (Radiofrequency Ionized Argon Gas) Endometrial Ablation Device
Device Trade Name:	MinervaTm Endometrial Ablation System
Device Procode:	MNB
Applicant's Name and Address:	Minerva Surgical, Inc. 101 Saginaw Drive Redwood City, CA 94063
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P140013
Date of FDA Notice of Approval:	July 27, 2105
Priority Review:	No

II. INDICATIONS FOR USE

The Minerva Endometrial Ablation System is indicated to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive menstrual bleeding) due to benign causes for whom childbearing is complete.

III. CONTRAINDICATIONS

The Minerva Endometrial Ablation System is contraindicated for use in the following:

- A patient who is pregnant or who wants to become pregnant in the future. PREGNANCIES FOLLOWING ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND FETUS.
- A patient with known or suspected (uterine cancer) or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- A patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Minerva procedure) or pathologic condition (e.g., requiring long-term medical therapy) that could lead to weakening of the myometrium.

* * *

2. Effectiveness Results

The analysis of effectiveness was based on the 110 evaluable subjects at the 12-month time point. Key effectiveness outcomes are presented in Table 4 and Table 5.

Based on the success rate of 91.8% with a 95% confidence interval (CI) of (85.0%, 96.2%) observed in the Minerva ITT population, the null hypothesis was rejected at the significance level of 5%, and the 12-month follow-up success rate observed with the Minerva Endometrial Ablation System was demon-

strated to be statistically significantly greater than the OPC of 66% (p-value <0.0001).

This analysis did not compare the success rate of the Minerva Endometrial Ablation Device to the individual success rates of the five approved endometrial ablation devices used to set the OPC.

Table 2 summarizes the effectiveness outcomes from the single arm study.

Table 2 Effectiveness outcomes from single arm study

	MINERVA™ N (% OF 110)
Number of successful patients (diary score < 75)	101
Study success rate (% patients with PBLAC score < 75) — Non-Proportional (Traditional) Method[1]	91.8%
Study success rate (% patients with PBLAC score < 75) — Proportional Method	87.3%
Number of patients reporting amenorrhea (PBLAC score=0)	73
Amenorrhoea rate (% patients with PBLC score = 0)	66 4%

[1] The success rate compared to the OPC. See discussion of non-proportion (traditional) versus proportional method below.

When using the PBLAC scoring method, subjects in the single arm study compared the appearances of their catamenial products (pads and tampons) to a set of pictures/icons. To calibrate these icons with the blood volume absorbed by catamenial products used in this study, expired diluted human blood was applied in 0.5 ml increments to the catamenial products to determine the minimum and maximum amount of blood needed to produce each icon on the PBLAC (i.e., heavy, moderate and light staining). This yielded a range of volumes for each icon. The process was repeated five times by the same investigator, yielding 15 scores for each pad/tampon. The mean volume was determined for each icon for each pad/tampon. The applicant used the mean volumes for the icons for one brand of pads as the baseline for the PBLAC scores. The scores for the icons for the other brands of pads were then calibrated using an "adjustment factor." The purpose of this adjustment factor is to account for the variability across pads. This method is referred to as the non-proportional or traditional method.

To evaluate whether the PBLAC instrument could be appropriately applied in the study, two investigators and ten female observers were randomly assigned catamenial products with known amounts of expired diluted blood applied. The

* * *

SUMMARY OF SAFETY AND EFFECTIVENESS DATA:

NovaSure™ Impedance Controlled Endometrial Ablation System

I. GENERAL INFORMATION

DEVICE GENERIC NAME:	Thermal (Radio-Frequency) Endometrial Ablation Device
DEVICE TRADE NAME:	NovaSureTM Impedance Controlled Endometrial Ablation System
APPLICANT'S NAME AND ADDRESS:	Novacept, Inc. 1047 Elwell Court Palo Alto, CA 94303
PREMARKET APPROVAL APPLICATION (PMA) NUMBER:	P010013
DATE OF PANEL RECOMMENDATION:	N/A

II. INDICATIONS FOR USE

The NovaSure™ System is intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

III. CONTRAINDICATIONS

Use of the NovaSure™ Impedance Controlled Endometrial Ablation System (hereafter referred to as the NovaSure™ System) is contraindicated for patients with the following conditions:

- A patient who is pregnant or who wants to become pregnant in the future. Pregnancies following ablation can be dangerous for both mother and fetus.
- A patient with known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium, such as unresolved adenomatous hyperplasia.
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean section or transmural myomectomy.

* * *

These issues were addressed with minor modifications made during the incorporation of the Cavity Integrity Assessment system into the device.

- Patient Accountability

A total of 265 subjects were enrolled in the study. Table 2C identifies the numbers of patients at key points of the study.

TABLE 2C. PATIENT ACCOUNTABILITY

NUMBER OF PATIENTS	NOVASURE™	LOOP RESECTION PLUS ROLLERBALL
Entered into study	175	90
Aborted procedures—uterine size or shape*	4	0
Aborted procedures—uterine perforation*	0	2
Treated	171	88
Failed — required additional treatment*	4	2
Hysterectomy performed*	2	2
Lost to follow-up*	2	2
Hodgkin's disease diagnosed post treatment*	1	0
6-Month Follow-up	162	82
Hysterectomy performed*	1	0
Pelvic pain — administered leuprolide*	1	0
Lost to follow-up*	4	0
12-Month Follow-up	156	82

* Discontinued patients

- Efficacy at One Year: Diary Scores

Patient success was based on a reduction in diary score from >150 pre-treatment to <75 at one year. Effectiveness rates were based on the Intent-to-Treat population.

TABLE 3— EFFECTIVENESS*:
DIARY SCORES AT 1 YEAR

	NOVASURE™ n(% OF 175)	LOOP RESECTION PLUS ROLLERBALL n (% of 90)
Number of successful patients (diary score<75)	136	67
Study success rate (% patients with score <75)	77.7%	74.4%
Number of patients with amenorrhea (score=0)	63	29
Amenorrhea rate (% patients with score=0)	36.0%	32.2%

* * *

No. 20-440

IN THE

Supreme Court of the United States

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL APPENDIX

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[Additional counsel listed on inside cover.]

PETITION FOR CERTIORARI FILED SEPT. 30, 2020
CERTIORARI GRANTED JAN. 8, 2021

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Counsel for Petitioner

TABLE OF CONTENTS

NOTICE

The following documents have been omitted from the printing of this Joint Appendix. They may be found in the Appendix to the Petition for a Writ of Certiorari at the following pages:

November 21, 2014

Mr. Csaba Truckai
19566 Arden Court
Saratoga, CA 95070

Re: Request for Signature – Hologic Inventor Declaration for 13.003011 US CON 7

Dear Mr. Truckai,

My name is Mandy Callahan and I work with the patent group in the legal department at Hologic. On August 13, 2013, we filed the 7th U.S. continuation in the above identified family of applications, entitled "Moisture Transport System for Contact Electrocoagulation." Due to new USPTO rules which went into effect in September 2012, the declaration you previously executed along with your co-contributors in the parent case is no longer acceptable for new continuation filings. As such, I wish to kindly request that you sign a new declaration (enclosed) which conforms to the new requirements and send it back to me in the pre-paid and pre-addressed Federal Express envelope provided herein at your earliest convenience. As a reference, I have also attached a copy of the application as published in February 2014.

Many thanks in advance for your assistance and please don't hesitate to contact me (or our in-house counsel, Robert Smith – 508-263-8491) with any questions.

Best regards,

Mandy Callahan

Mandy Callahan
IP Paralegal

Enc.

HOLOGIC

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PTX-0114
1:15-cv-01031-JFB-SRF

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Moisture Transport System for Contact Electrocoagulation

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 13/962,178 filed on August 8, 2013.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Csaba Truckai Date (Optional) :_____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

US 20140046317A1

(19) **United States**

(12) **Patent Application Publication**

Truckai et al.

(10) **Pub. No.: US 2014/0046317 A1**

(43) **Pub. Date: Feb. 13, 2014**

(54) **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

(71) Applicant: **Cytyc Surgical Products**, Marlborough, MA (US)

(72) Inventors: **Csaba Truckai**, Sunnyvale, CA (US); **Russel Mahlon Sampson**, Mountain View, CA (US); **Stephanie Squarcia**, Palo Alto, CA (US); **Alfonso Lawrence Ramirez**, San Jose, CA (US); **Estela Hilario**, Los Altos, CA (US)

(73) Assignee: **Cytyc Surgical Products**, Marlborough, MA (US)

(21) Appl. No.: **13/962,178**

(22) Filed: **Aug. 8, 2013**

Related U.S. Application Data

(60) Continuation of application No. 12/581,506, filed on Oct. 19, 2009, now Pat. No. 8,506,563, which is a continuation of application No. 10/959,771, filed on Oct. 6, 2004, now Pat. No. 7,604,633, which is a division of application No. 09/103,072, filed on Jun. 23, 1998, now Pat. No. 6,813,520, which is a continuation-in-part of application No. 08/632,516, filed on Apr. 12, 1996, now Pat. No. 5,769,880.

(60) Provisional application No. 60/084,791, filed on May 8, 1998.

Publication Classification

(51) **Int. Cl.**

A61B 18/18 (2006.01)

A61B 17/42 (2006.01)

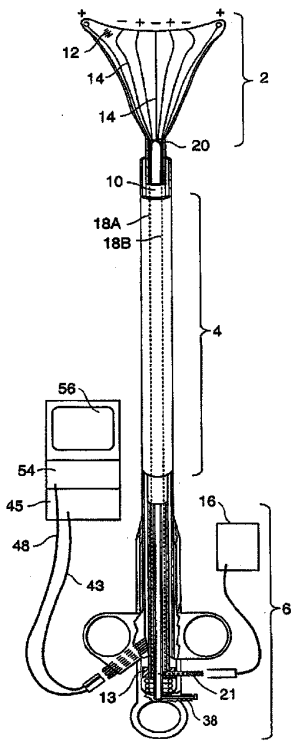
(52) **U.S. Cl.**

CPC ***A61B 18/18*** (2013.01); ***A61B 17/42*** (2013.01)

USPC **606/33**; 606/119

(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.



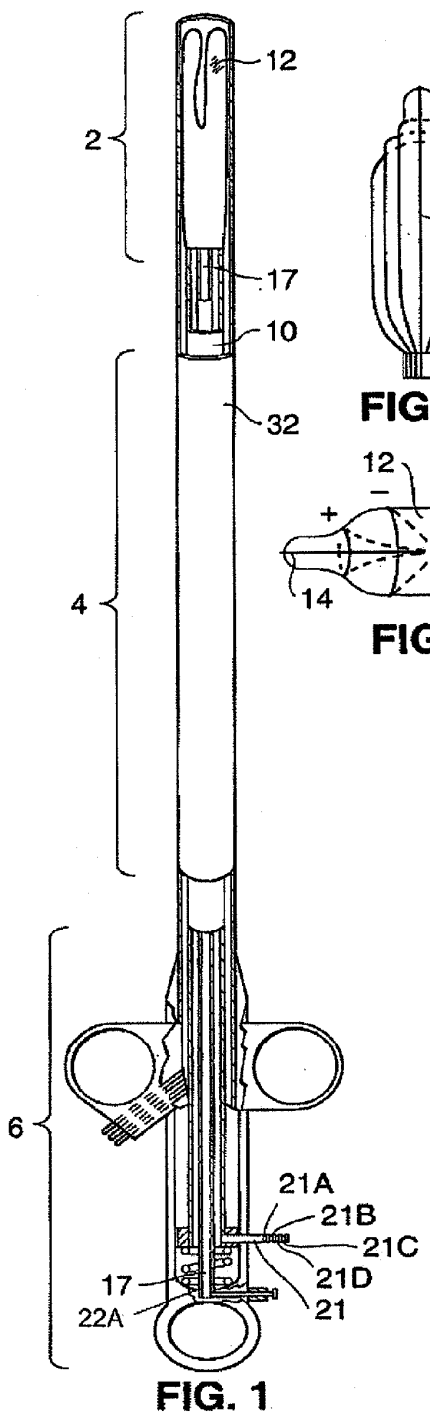


FIG. 1

FIG. 3

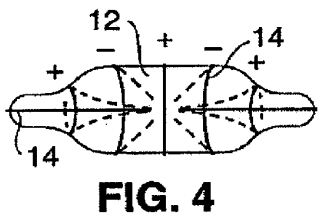


FIG. 4

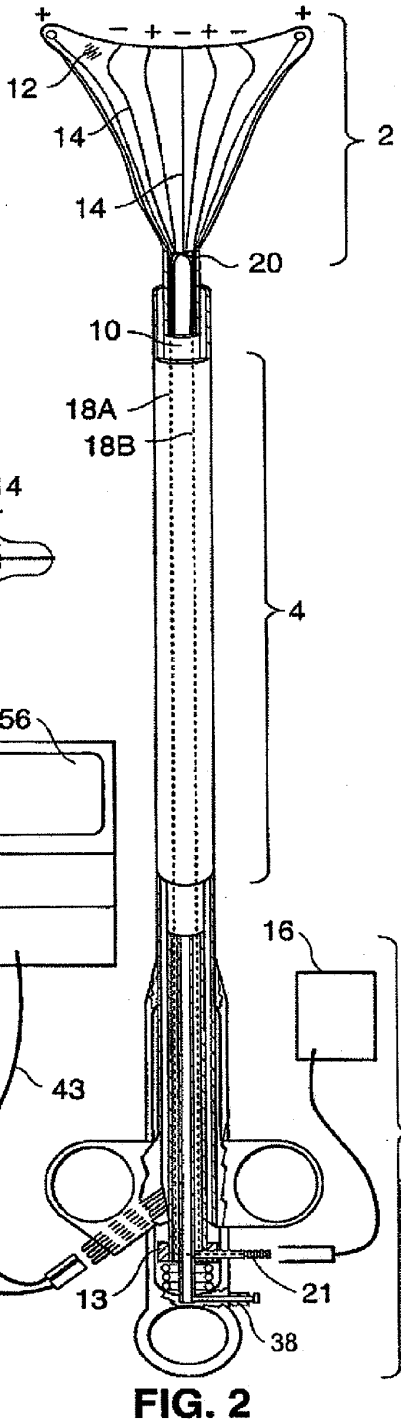
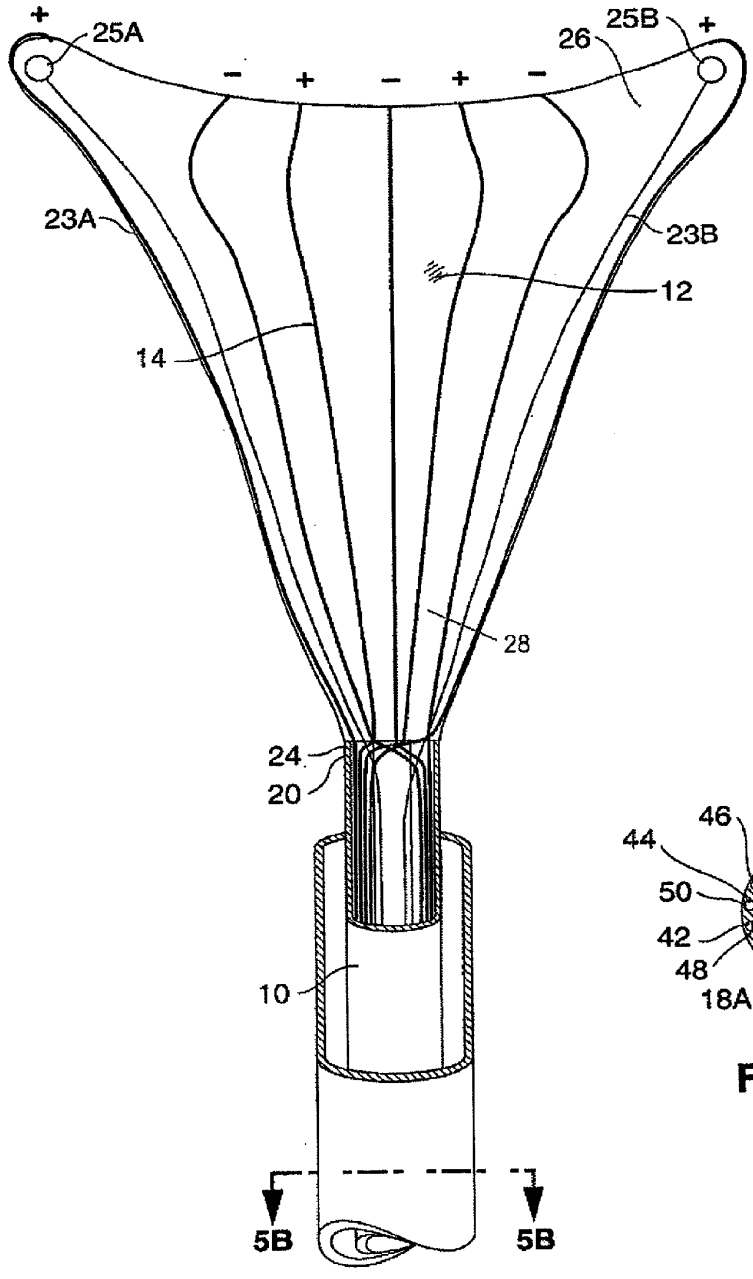


FIG. 2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26
25B
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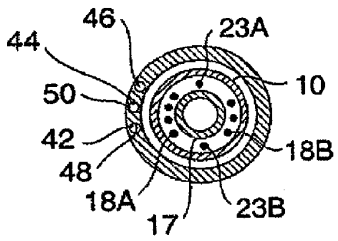
23A
23B
12
14
28
24
20
10
5B
5B

FIG. 5A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23A
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50
42
18B
48
18A
17
23B

FIG. 5B

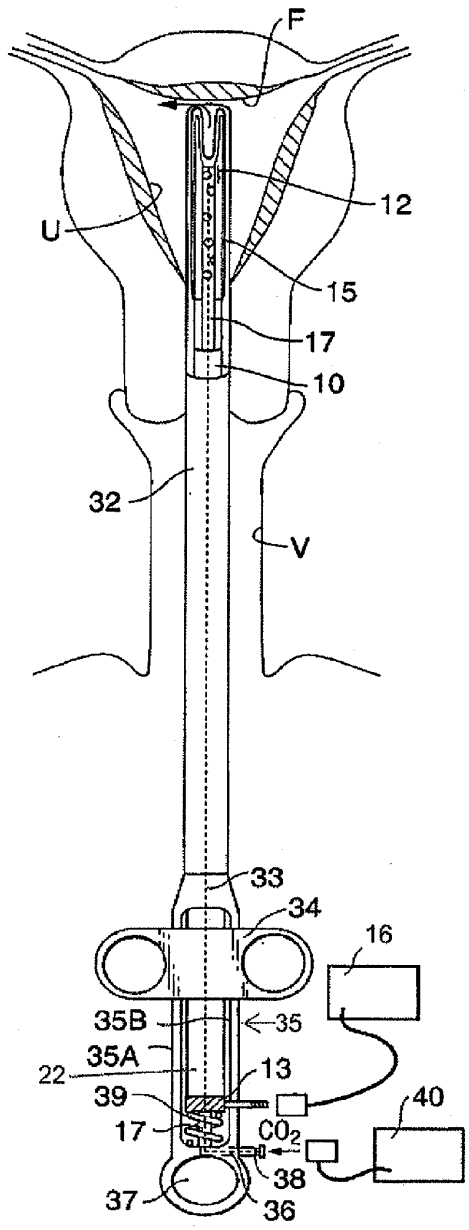
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FIG. 6

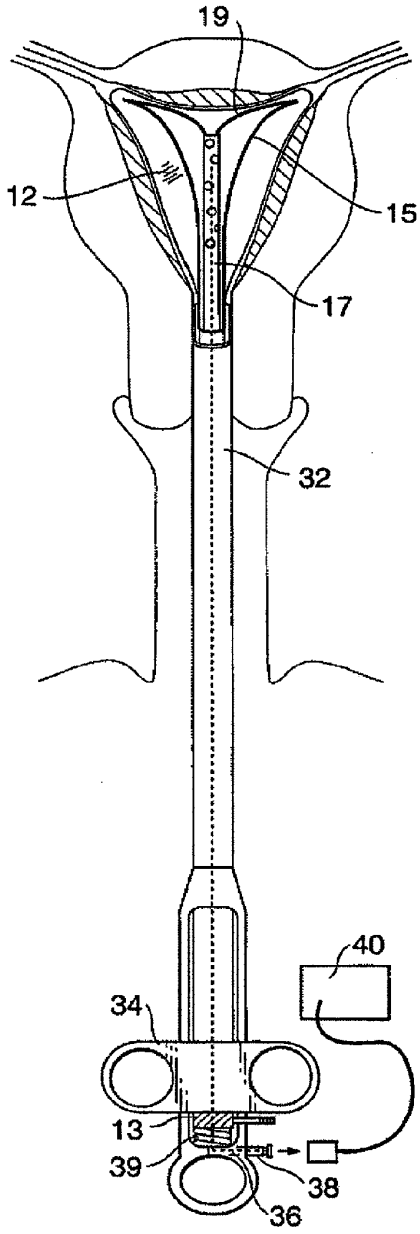
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FIG. 7

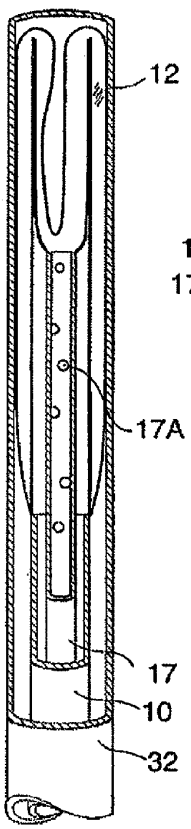

FIG. 8

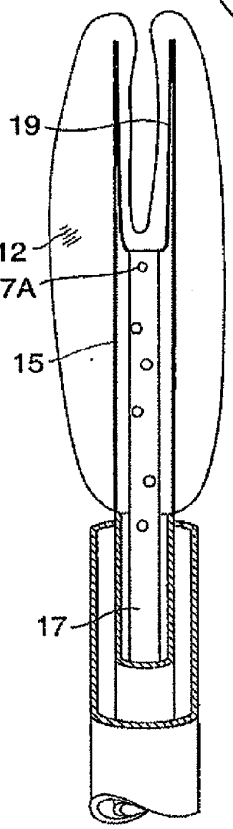

FIG. 9

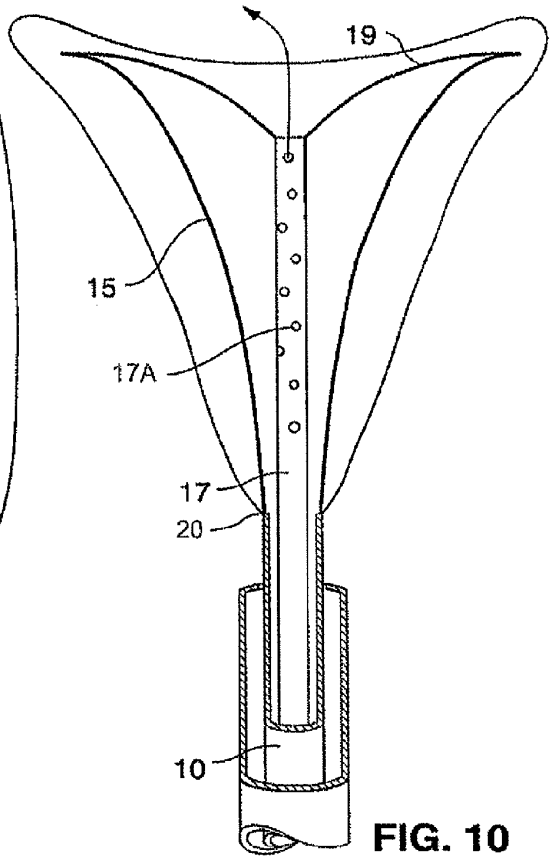

FIG. 10

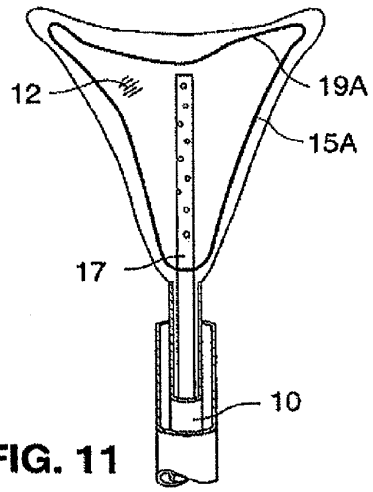

FIG. 11

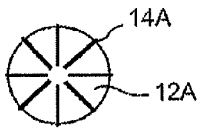

FIG. 13

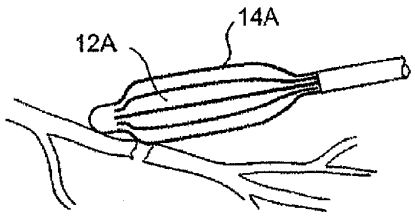

FIG. 14

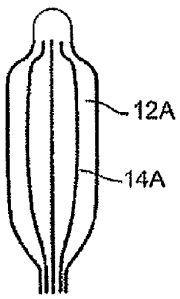

FIG. 12

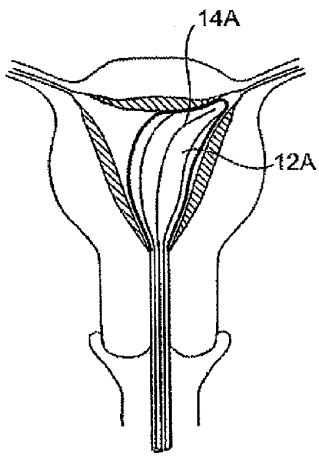

FIG. 15

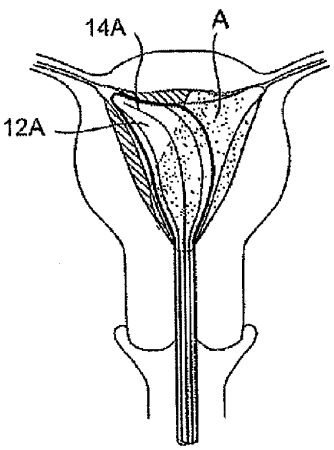

FIG. 16

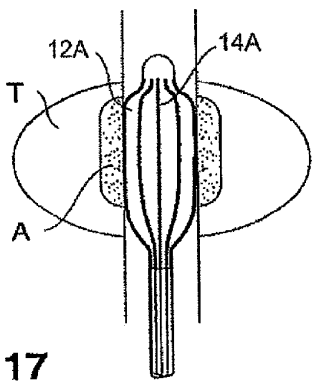

FIG. 17

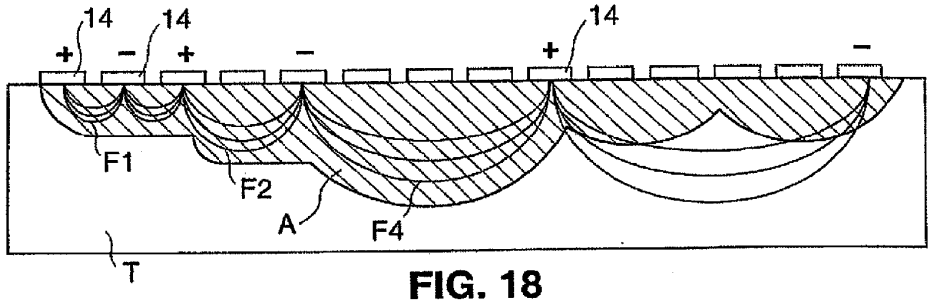

FIG. 18

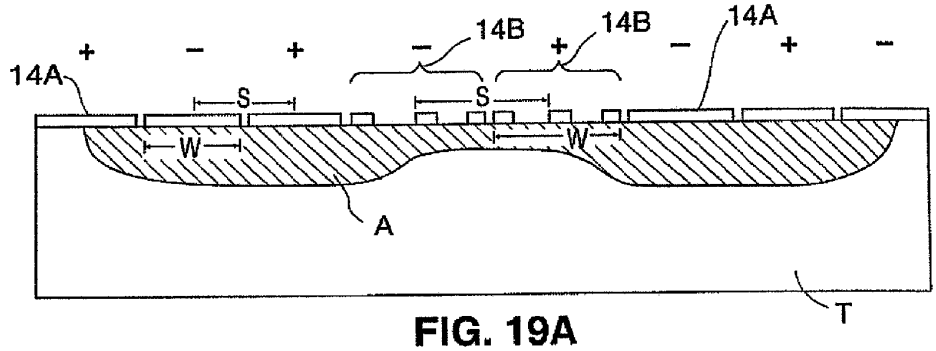

FIG. 19A

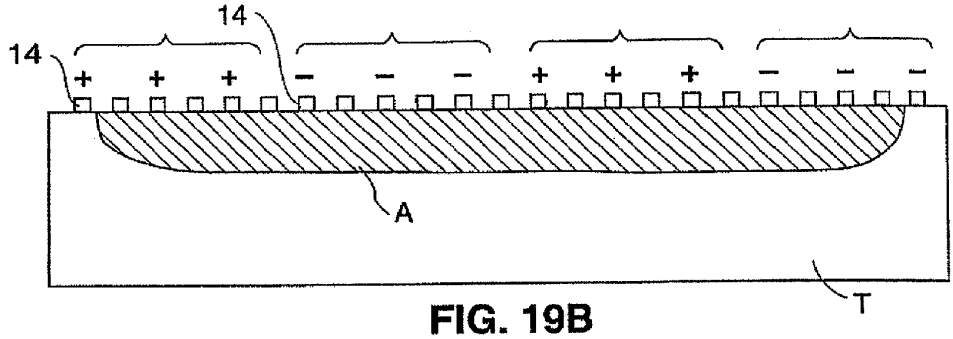

FIG. 19B

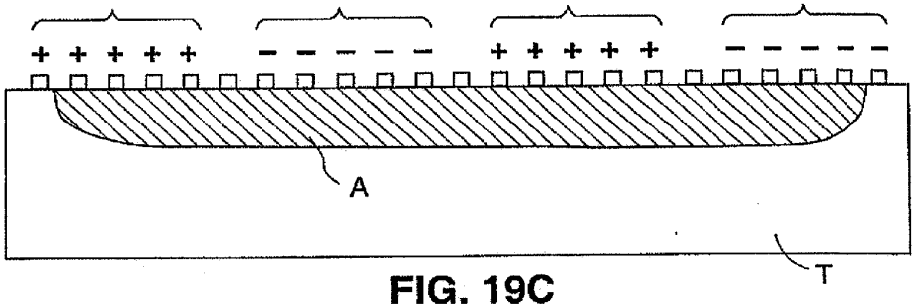

FIG. 19C

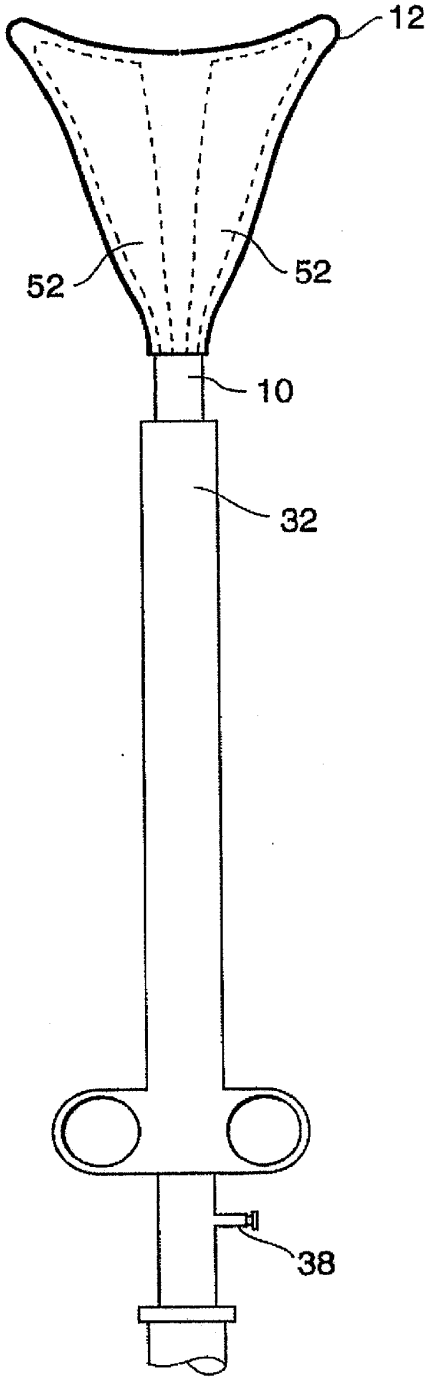

FIG. 20

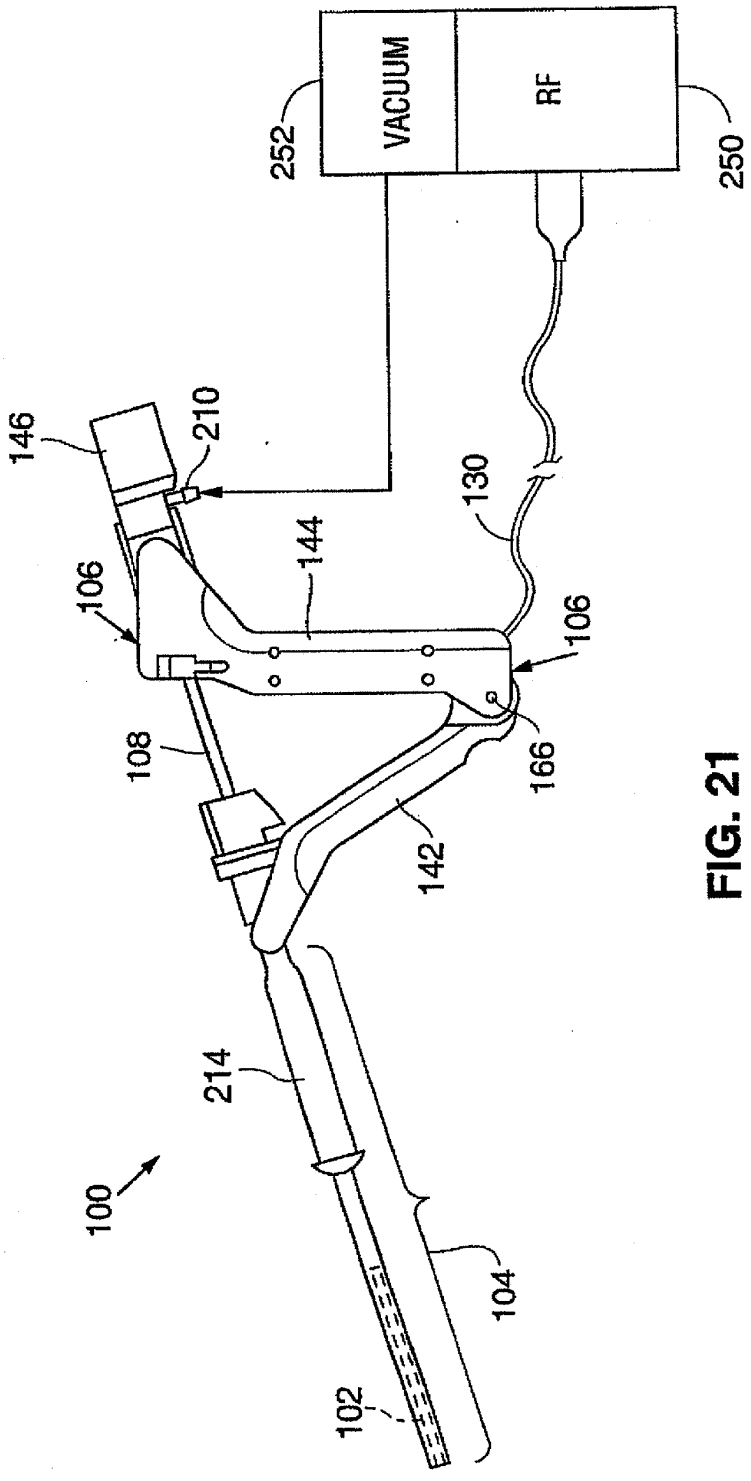
VACUUM
RF
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FIG. 21

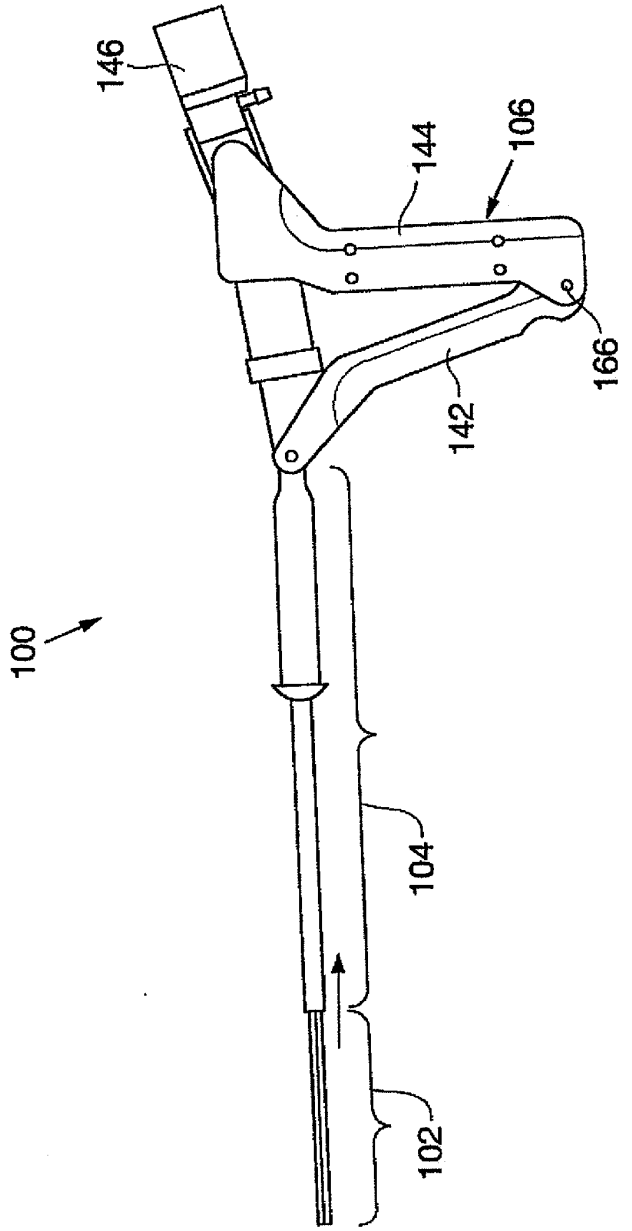

FIG. 22

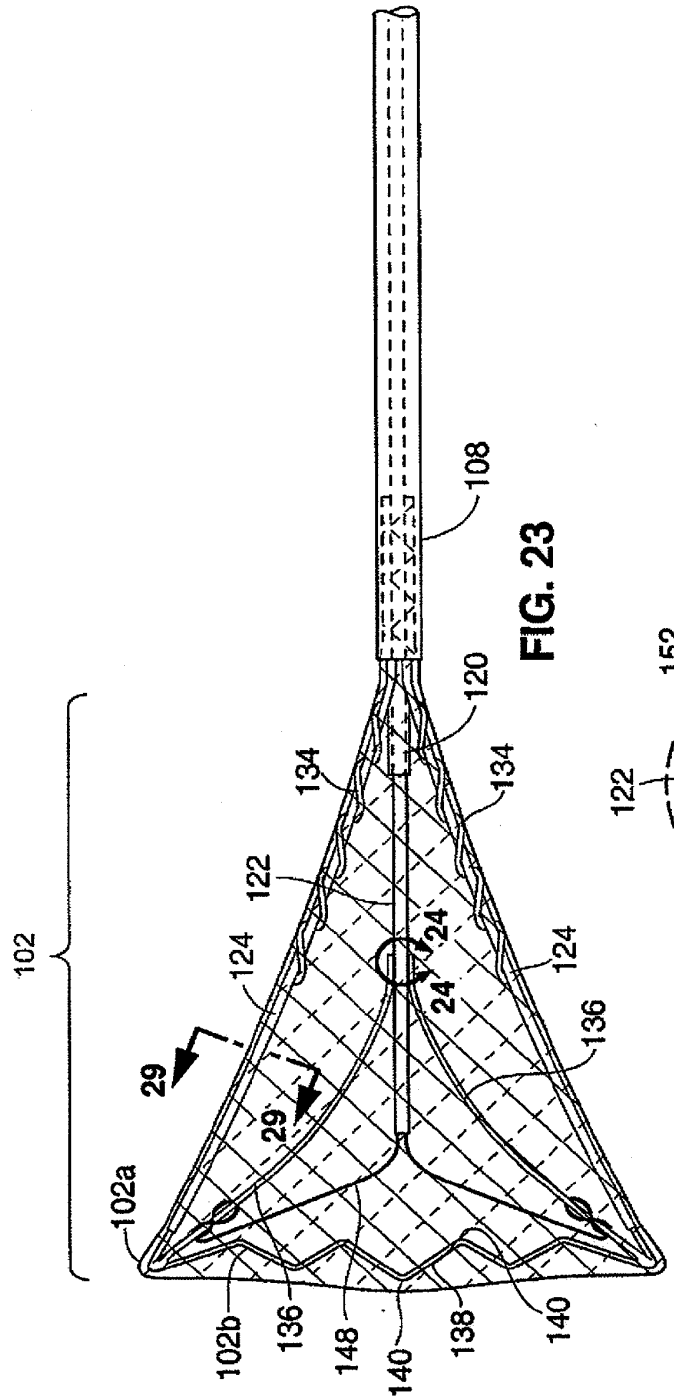
108
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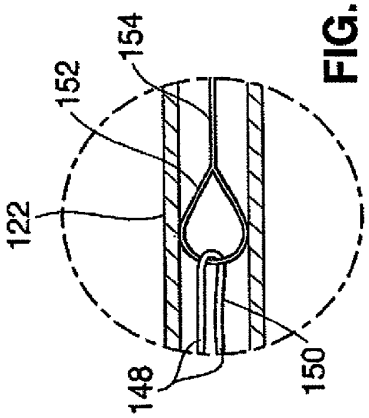
FIG. 23


154
152
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148
150

FIG. 24

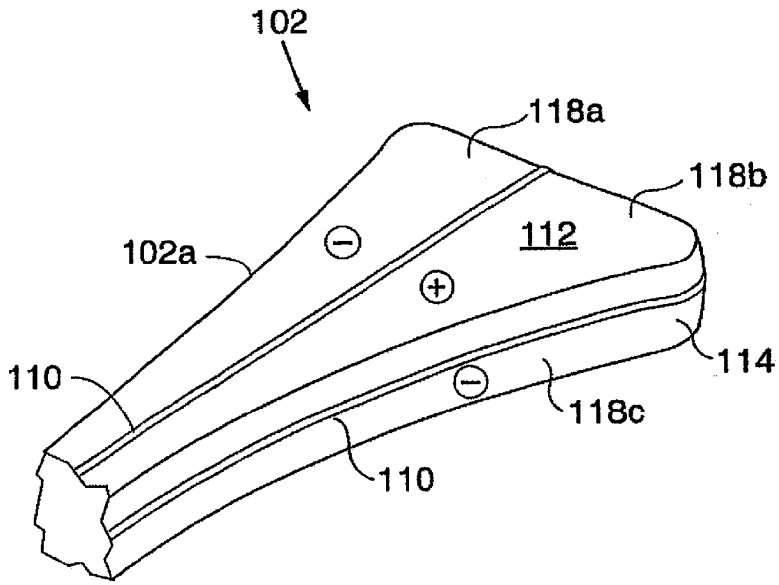

FIG. 25A

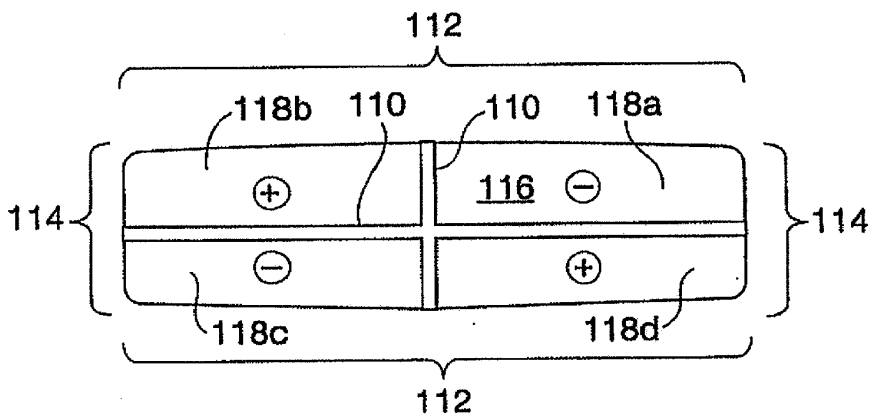

FIG. 25B

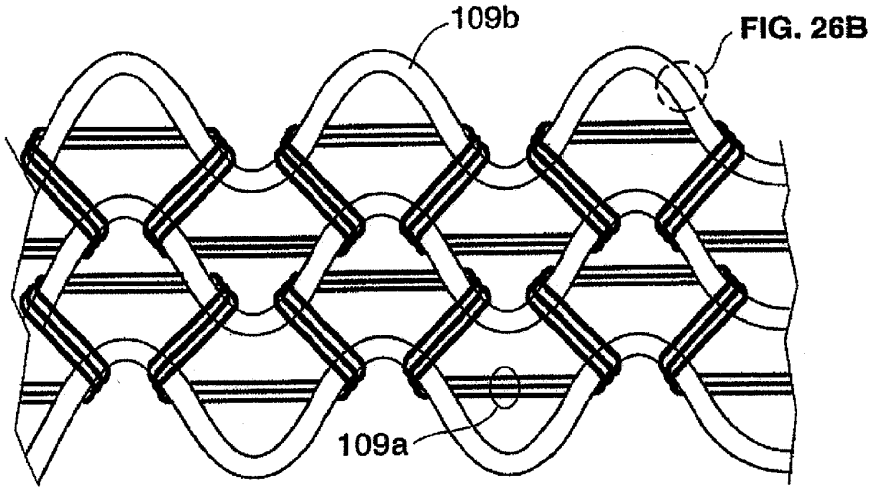

FIG. 26A

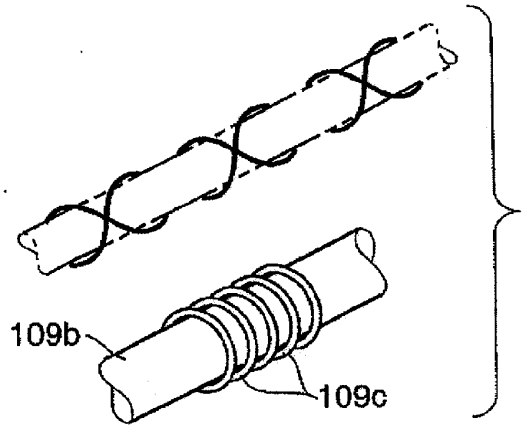

FIG. 26B

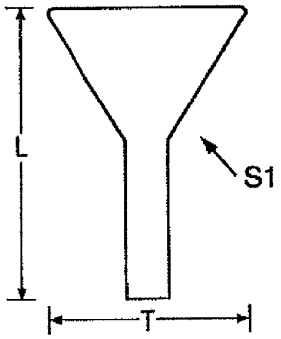

FIG. 27A

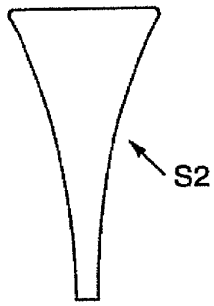

FIG. 27B

FIG. 27C

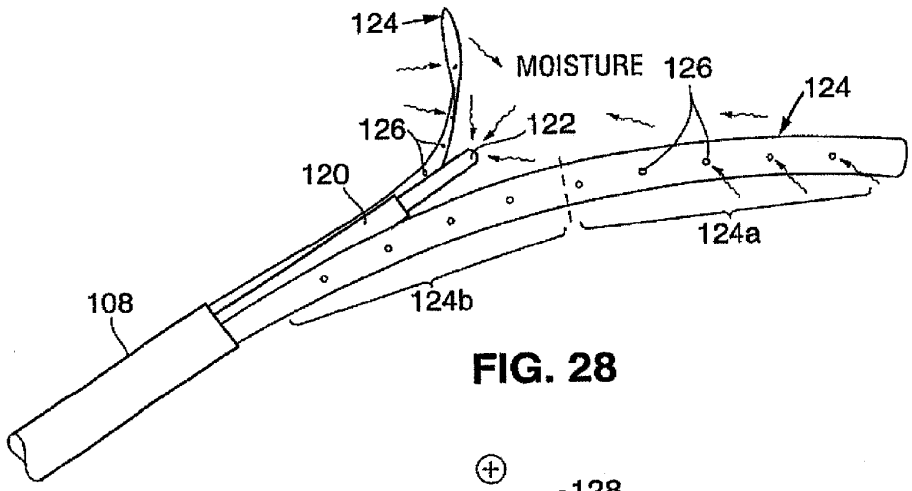

FIG. 28

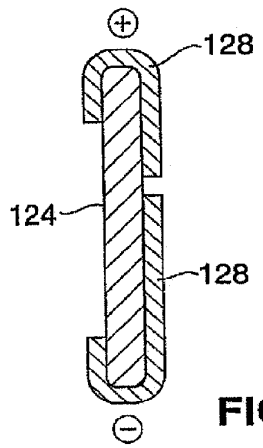

FIG. 29

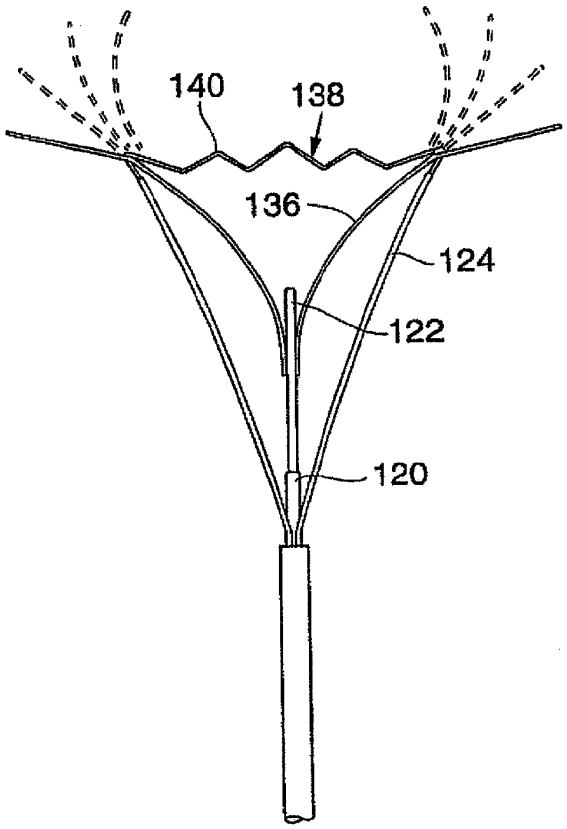

FIG. 30

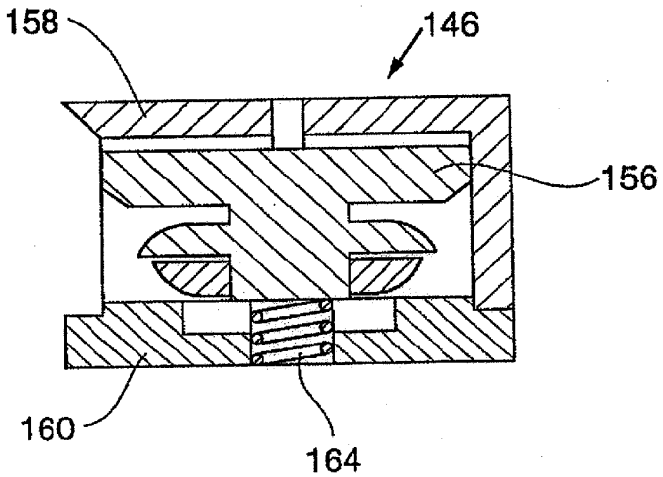

FIG. 31

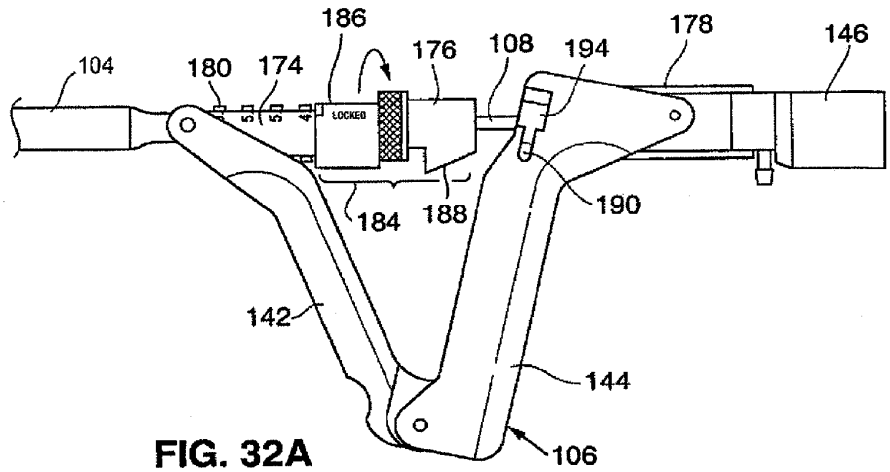

FIG. 32A

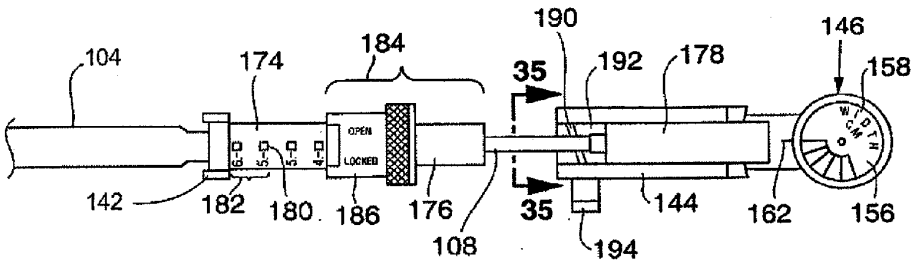

FIG. 32B

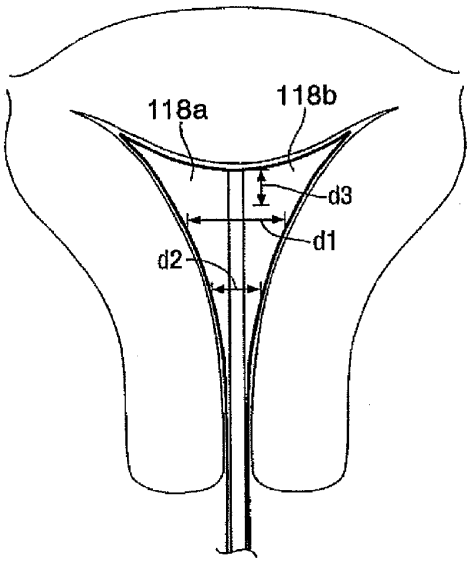

FIG. 33

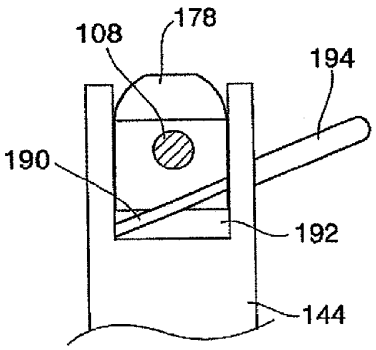

FIG. 35

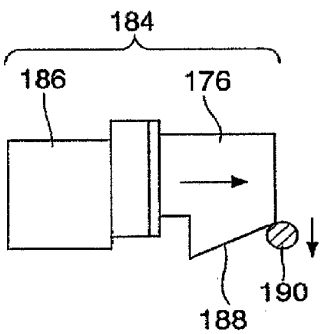

FIG. 36A

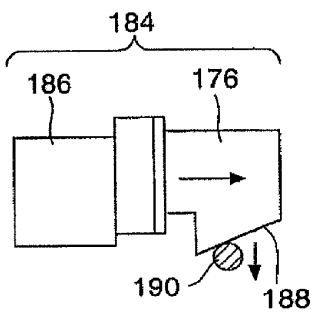

FIG. 36B

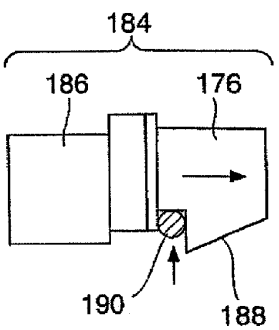

FIG. 36C

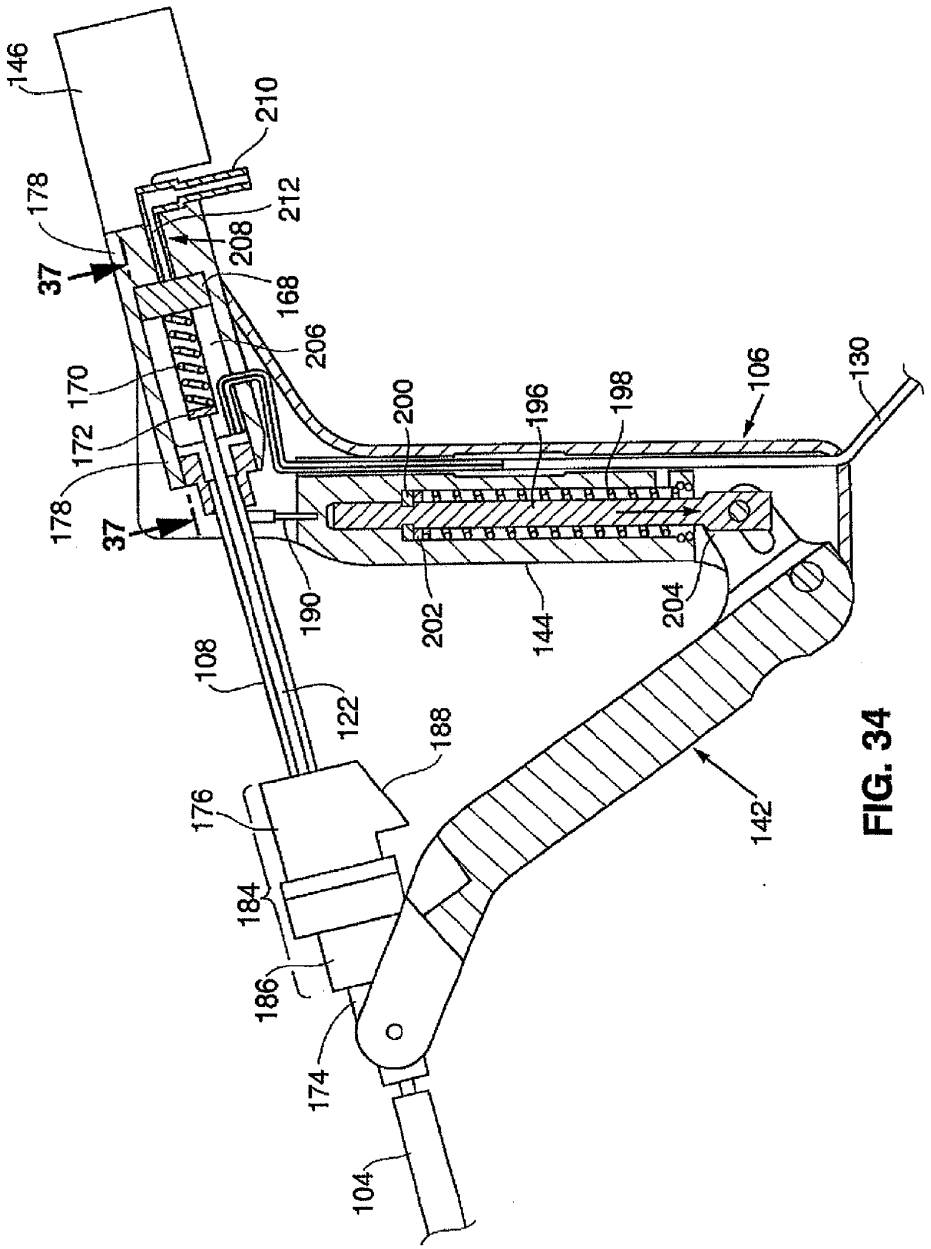
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FIG. 34

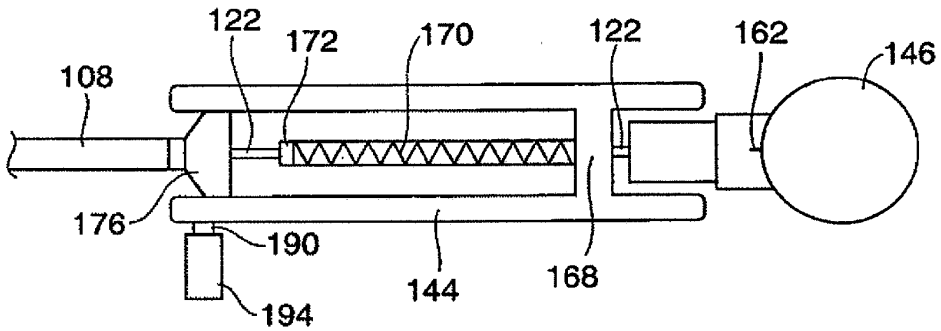

FIG. 37A

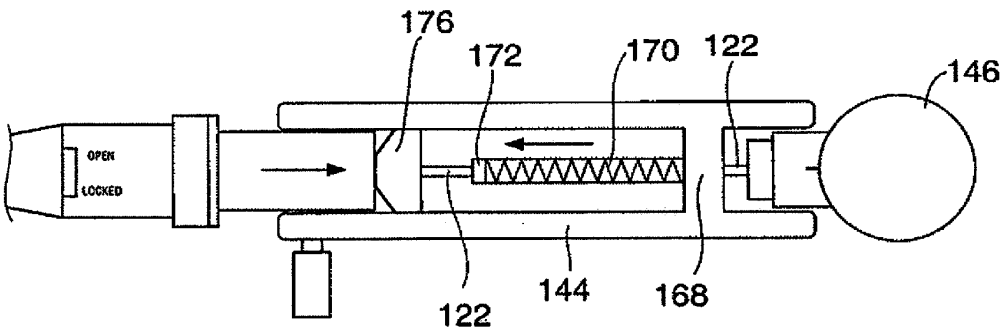

FIG. 37B

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 12/581,506 filed Oct. 19, 2009, now U.S. Pat. No. 8,506,563 which is a continuation of U.S. application Ser. No. 10/959,771 filed Oct. 6, 2004, now U.S. Pat. No. 7,604,633, which is a divisional of U.S. application Ser. No. 09/103,072 filed Jun. 23, 1998, now U.S. Pat. No. 6,813,520, which is a continuation-in-part of U.S. application Ser. No. 08/632,516 filed Apr. 12, 1996, now U.S. Pat. No. 5,769,880, and claims the benefit of U.S. provisional application 60/084,791 filed May 8, 1998.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.

BACKGROUND OF THE INVENTION

[0003] Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

[0004] U.S. Pat. No. 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Pat. No. 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

[0005] These ablation devices are satisfactory for carrying out ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only be done by assumption.

[0006] For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

[0007] Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation. Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C., the fluid within the tissue begins to boil and to thereby produce steam. Because ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

[0008] Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

[0009] Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

[0010] It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

SUMMARY OF THE INVENTION

[0011] The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. **1** is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

[0013] FIG. **2** is a front elevation view of the ablation device of FIG. **1**, with the handle shown in cross-section and with the RF applicator head in an open condition.

[0014] FIG. **3** is a side elevation view of the ablation device of FIG. **2**.

[0015] FIG. **4** is a top plan view of the ablation device of FIG. **2**.

[0016] FIG. **5**A is a front elevation view of the applicator head and a portion of the main body of the ablation device of FIG. **2**, with the main body shown in cross-section.

[0017] FIG. **5**B is a cross-section view of the main body taken along the plane designated **5**B-**5**B in FIG. **5**A.

[0018] FIG. **6** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

[0019] FIG. **7** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

[0020] FIG. **8** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the RF applicator head in the closed condition.

[0021] FIG. **9** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

[0022] FIG. **10** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

[0023] FIG. **11** is a cross-section view of a distal portion of an RF ablation device similar to FIG. **1** which utilizes an alternative spring member configuration for the RF applicator head.

[0024] FIG. **12** is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of FIG. **1**, which utilizes an RF applicator head having a modified shape.

[0025] FIG. **13** is a top plan view of the ablation device of FIG. **12**.

[0026] FIG. **14** is a representation of a bleeding vessel illustrating use of the ablation device of FIG. **12** for general bleeding control.

[0027] FIGS. **15** and **16** are representations of a uterus illustrating use of the ablation device of FIG. **12** for endometrial ablation.

[0028] FIG. **17** is a representation of a prostate gland illustrating use of the ablation device of FIG. **12** for prostate ablation.

[0029] FIG. **18** is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

[0030] FIGS. **19**A-**19**C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

[0031] FIG. **20** is a side elevation view, similar to the view of FIG. **2**, showing an ablation device according to the present invention in which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

[0032] FIG. **21** is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

[0033] FIG. **22** is a side elevation view of the ablation device of FIG. **21**, showing the array in the deployed state.

[0034] FIG. **23** is a top plan view of the applicator head of the apparatus of FIG. **21**.

[0035] FIG. **24** is a cross-sectional top view of the encircled region designated **24** in FIG. **23**.

[0036] FIG. **25**A is a perspective view of the electrode array of FIG. **23**.

[0037] FIG. **25**B is a distal end view of the applicator head of FIG. **30**A.

[0038] FIG. **26**A is a plan view of a knit that may be used to form the applicator head.

[0039] FIG. **26**B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of FIG. **26**A.

[0040] FIGS. **27**A, **27**B, **27**C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

[0041] FIG. **28** is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of FIG. **23**.

[0042] FIG. **29** is a cross-section view of a flexure taken along the plane designated **29**-**29** in FIG. **23**.

[0043] FIG. **30** is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

[0044] FIG. **31** is a cross-sectional side view of the bobbin portion of the apparatus of FIG. **21**.

[0045] FIG. **32**A is a side elevation view of the handle of the ablation device of FIG. **21**.

[0046] FIG. **32**B is a top plan view of the handle of the ablation device of FIG. **21**. For clarity, portions of the proximal and distal grips are not shown.

[0047] FIG. **33** illustrates placement of the applicator head according to the present invention in a uterine cavity.

[0048] FIG. **34** is a side elevation view of the handle of the ablation apparatus of FIG. **21**, showing portions of the apparatus in cross-section.

[0049] FIG. **35** is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated **35**-**35** in FIG. **32**B.

[0050] FIGS. **36**A, **36**B, and **36**C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

[0051] FIGS. **37**A and **37**B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated **37**-**37** in FIG. **34** and illustrating one of the load limiting features of the second embodiment. FIG. **37**A shows the condition of the compression spring before the heel member moves into abutment with frame member, and FIG. **37**B shows the condition of the spring after the heel member moves into abutment with the frame member.

DETAILED DESCRIPTION

[0052] The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION" (attorney docket no. ENVS-400); and U.S. Pro-

visional Patent Application No. 60/084,712 filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE" (attorney docket no. ENVS-500).

[0053] The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment

Structure

[0054] Referring to FIGS. **1** and **2**, an ablation device according to the present invention is comprised generally of three major components: RF applicator head **2**, main body **4**, and handle **6**. Main body **4** includes a shaft **10**. The RF applicator head **2** includes an electrode carrying means **12** mounted to the distal end of the shaft **10** and an array of electrodes **14** formed on the surface of the electrode carrying means **12**. An RF generator **16** is electrically connected to the electrodes **14** to provide mono-polar or bipolar RF energy to them.

[0055] Shaft **10** is an elongate member having a hollow interior. Shaft **10** is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar **13** is formed on the exterior of the shaft **10** at the proximal end. As best shown in FIGS. **6** and **7**, passive spring member **15** are attached to the distal end of the shaft **10**.

[0056] Extending through the shaft **10** is a suction/insufflation tube **17** (FIGS. **6-9**) having a plurality of holes **17***a* formed in its distal end. An arched active spring member **19** is connected between the distal ends of the passive spring members **15** and the distal end of the suction/insufflation tube **17**.

[0057] Referring to FIG. **2**, electrode leads **18***a* and **18***b* extend through the shaft **10** from distal end **20** to proximal end **22** of the shaft **10**. At the distal end **20** of the shaft **10**, each of the leads **18***a*, **18***b* is coupled to a respective one of the electrodes **14**. At the proximal end **22** of the shaft **10**, the leads **18***a*, **18***b* are electrically connected to RF generator **16** via an electrical connector **21**. During use, the leads **18***a*, **18***b* carry RF energy from the RF generator **16** to the electrodes. Each of the leads **18***a*, **18***b* is insulated and carries energy of an opposite polarity than the other lead.

[0058] Electrically insulated sensor leads **23***a*, **23***b* (FIGS. **5**A and **5**B) also extend through the shaft **10**. Contact sensors **25***a*, **25***b* are attached to the distal ends of the sensor leads **23***a*, **23***b*, respectively and are mounted to the electrode carrying means **12**. During use, the sensor leads **23***a*, **23***b* are coupled by the connector **21** to a monitoring module in the RF generator **16** which measures impedance between the sensors **25***a*, **25***b*. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

[0059] Referring to FIG. **5**B, electrode leads **18***a*, **18***b* and sensor leads **23***a*, **23***b* extend through the shaft **10** between the external walls of the tube **17** and the interior walls of the shaft **10** and they are coupled to electrical connector **21** which is preferably mounted to the collar **13** on the shaft **10**. Connector **21**, which is connectable to the RF generator **16**, includes at least four electrical contact rings **21***a*-**21***d* (FIGS. **1** and **2**) which correspond to each of the leads **18***a*, **18***b*, **23***a*, **23***b*. Rings **21***a*, **21***b* receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings **21***c*, **21***d* deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator **16**.

[0060] Referring to FIG. **5**A, the electrode carrying means **12** is attached to the distal end **20** of the shaft **10**. A plurality of holes **24** may be formed in the portion of the distal end **20** of the shaft which lies within the electrode carrying means **12**.

[0061] The electrode carrying means **12** preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in FIGS. **1** through **11** has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means **12** shown in these figures includes horn regions **26** which during use are positioned within the cornual regions of the uterus and which therefore extend towards the fallopian tubes.

[0062] Electrode carrying means **12** is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

[0063] Electrodes **14** are preferably attached to the outer surface of the electrode carrying means **12**, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means **12** by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means **12** is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

[0064] The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

[0065] The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

[0066] For example, by using 3-6 mm spacing and an electrode width of approximately 0.5-2.5 mm, delivery of approximately 20-40 watts over a 9-16 cm2 target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

[0067] By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2-3 mm when the active electrode surfaces covers less than 1% of the target tissue area. This can be better understood with reference to FIG. **19**A, in which high surface density electrodes are designated **14***a* and low surface density electrodes are designated **14***b*. For purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in FIG. **19**A.

[0068] As is apparent from FIG. **19**A, the electrodes **14***a*, which have more active area in contact with the underlying tissue T, produce a region of ablation **A1** that extends more deeply into the tissue T than the ablation region **A2** produced by the low density electrodes **14***b*, even though the electrode spacings and widths are the same for the high and low density electrodes.

[0069] Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	1-3 mm
1-2.5 mm	3-6 mm	5-7 mm
1-4.5 mm	8-10 mm	8-10 mm

[0070] Examples of electrode widths, having spacings with less than 1% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	0.5-1 mm
1-2.S mm	3-6 mm	2-3 mm
1-4.5 mm	8-10 mm	2-3 mm

[0071] Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

[0072] In the preferred embodiment, the preferred electrode spacing is approximately 8-10 mm in the horn regions **26** with the active electrode surfaces covering approximately 1% of the target region. Approximately 1-2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated **28**) and approximately 3-6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

[0073] The RF generator **16** may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to FIG. **18**.

[0074] Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes may be arranged in any pattern to provide ablation to desired depths.

[0075] Referring to FIGS. **6** and **7**, an introducer sheath **32** facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath **32** is a tubular member which is telescopically slidable over the shaft **10**. The sheath **32** is slidable between a distal condition, shown in FIG. **6**, in which the electrode carrying means **12** is compressed inside the sheath, and a proximal condition in which the sheath **32** is moved proximally to release the electrode carrying means from inside it (FIG. **7**). By compressing the electrode carrying means **12** to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

[0076] A handle **34** attached to the sheath **32** provides finger holds to allow for manipulation of the sheath **32**. Handle **34** is slidably mounted on a handle rail **35** which includes a sleeve **33**, a finger cutout **37**, and a pair of spaced rails **35***a*, **35***b* extending between the sleeve **33** and the finger cutout **37**. The shaft **10** and sheath **32** slidably extend through the sleeve **33** and between the rails **35***a*, **35***b*. The tube **17** also extends through the sleeve **33** and between the rails **35***a*, **35***b*, and its proximal end is fixed to the handle rail **35** near the finger cutout **37**.

[0077] A compression spring **39** is disposed around the proximal most portion of the suction/insufflation tube **17** which lies between the rails **35***a*, **35***b*. One end of the compression spring **39** rests against the collar **13** on the shaft **10**, while the opposite end of the compression spring rests against the handle rail **35**. During use, the sheath **32** is retracted from the electrode carrying means **12** by squeezing the handle **34** towards the finger cutout **37** to slide the sheath **32** in the distal direction. When the handle **34** advances against the collar **13**, the shaft **10** (which is attached to the collar **13**) is forced to slide in the proximal direction, causing compression of the spring **39** against the handle rail **35**. The movement of the shaft **10** relative to the suction/insufflation tube **17** causes the shaft **10** to pull proximally on the passive spring member **15**. Proximal movement of the passive spring member **15** in turn pulls against the active spring member **19**, causing it to move to the opened condition shown in FIG. **7**. Unless the shaft is held in this retracted condition, the compression spring **39** will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

[0078] The amount by which the springs **15**, **19** are spread may be controlled by manipulating the handle **34** to slide the shaft **10** (via collar **13**), proximally or distally. Such sliding movement of the shaft **10** causes forceps-like movement of the spring members **15**, **19**.

[0079] A flow pathway **36** is formed in the handle rail **35** and is fluidly coupled to a suction/insufflation port **38**. The proximal end of the suction/insufflation tube **17** is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube **17** via the suction/insufflation port **38**. For example, suction may be applied to the fluid port **38** using a suction/insufflation unit **40**. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means **12**, into

the suction/insufflation tube **17** via holes **17***a*, through the tube **17**, and through the suction/insufflation unit **40** via the port **38**. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube **17** via the port **38**. The insufflation gas travels through the tube **17**, through the holes **17***a*, and into the uterine cavity through the permeable electrode carrying member **12**.

[0080] If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen **42**, **44**, and **46** may be formed in the walls of the introducer sheath **32** as shown in FIG. **5**B. An imaging conduit, such as a fiberoptic cable **48**, extends through lumen **42** and is coupled via a camera cable **43** to a camera **45**. Images taken from the camera may be displayed on a monitor **56**. An illumination fiber **50** extends through lumen **44** and is coupled to an illumination source **54**. The third lumen **46** is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

[0081] Because during use it is most desirable for the electrodes **14** on the surface of the electrode carrying means **12** to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means **12** may be provided to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

[0082] For example, referring to FIG. **11**, alternative spring members **15***a*, **19***a* may be attached to the shaft **10** and biased such that, when in a resting state, the spring members are positioned in the fully resting condition shown in FIG. **11**. Such spring members would spring to the resting condition upon withdrawal of the sheath **32** from the RF applicator head **2**.

[0083] Alternatively, a pair of inflatable balloons **52** may be arranged inside the electrode carrying means **12** as shown in FIG. **20** and connected to a tube (not shown) extending through the shaft **10** and into the balloons **52**. After insertion of the apparatus into the organ and following retraction of the sheath **32**, the balloons **52** would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port **38** using an apparatus similar to the suction/insufflation apparatus **40**.

[0084] Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end **22***a* of the suction/insufflation tube **17**. Application of suction using the suction/insufflation device **40** would draw the organ tissue towards the electrode carrying means **12** and thus into better contact with the electrodes **14**.

[0085] FIGS. **12** and **13** show an alternative embodiment of an ablation device according to the present invention. In the alternative embodiment, an electrode carrying means **12***a* is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (FIG. **14**), tissue ablation in the prostate gland (FIG. **17**), and also intrauterine ablation (FIGS. **15** and **16**).

First Exemplary Embodiment

Operation

[0086] Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

[0087] Referring to FIG. **1**, the device is initially configured for use by positioning the introducer sheath **32** distally along the shaft **10**, such that it compresses the electrode carrying means **12** within its walls.

[0088] At this time, the electrical connector **21** is connected to the RF generator **16**, and the fiberoptic cable **48** and the illumination cable **50** are connected to the illumination source, monitor, and camera, **54**, **56**, **45**. The suction/insufflation unit **40** is attached to suction/insufflation port **38** on the handle rail **35**. The suction/insufflation unit **40** is preferably set to deliver carbon dioxide at an insufflation pressure of 20-200 mmHg.

[0089] Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in FIG. **6**, until the distal end of the introducer sheath **32** contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube **17** via the port **38**, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera **45** and monitor **56**) the internal cavities using images detected by a fiberoptic cable **48** inserted through lumen **42**. If, upon observation, the physician determines that a tissue biopsy or other procedure is needed, the required instruments may be inserted into the uterine cavity via the instrument channel **46**.

[0090] Following insertion, the handle **34** is withdrawn until it abuts the collar **13**. At this point, the sheath **32** exposes the electrode carrying member **12** but the electrode carrying member **12** is not yet fully expanded (see FIG. **9**), because the spring members **15**, **19** have not yet been moved to their open condition. The handle **34** is withdrawn further, causing the shaft **10** to move proximally relative to the suction/insufflation tube **17**, causing the passive spring members **15** to pull the active spring members **19**, causing them to open into the opened condition shown in FIG. **10**.

[0091] The physician may confirm proper positioning of the electrode carrying member **12** using the monitor **56**, which displays images from the fiberoptic cable **48**.

[0092] Proper positioning of the device and sufficient contact between the electrode carrying member **12** and the endometrium may further be confirmed using the contact sensors **25***a*, **25***b*. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20-180 ohm, depending on the water content of the endometrial lining.

[0093] The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member **12**, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors **25***a*, **25***b* that there is sound contact between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

[0094] Next, insufflation is terminated. Approximately 1-5 cc of saline may be introduced via suction/insufflation tube **17** to initially wet the electrodes and to improve electrode elec-

trical contact with the tissue. After introduction of saline, the suction/insufflation device **40** is switched to a suctioning mode. As described above, the application of suction to the RF applicator head **2** via the suction/insufflation tube **17** collapses the uterine cavity onto the RF applicator head **2** and thus assures better contact between the electrodes and the endometrial tissue.

[0095] If the generally tubular apparatus of FIGS. **12** and **13** is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. FIGS. **15** and **16**.

[0096] Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in FIG. **5***a*, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F**1**, F**2** and F**4** in FIG. **18**, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in FIG. **18**, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F**2** which results from energization of electrodes having a non-energized electrode between them, or pattern F**4** which results from energization of electrodes having three non-energized electrodes between them).

[0097] Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see FIG. **19**A). Referring to FIG. **19**B, if multiple, closely spaced, electrodes **14** are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in FIG. **19**B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

[0098] As another example, shown in FIG. **19**C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

[0099] As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member **12** and is thereby drawn away from the electrodes. The moisture may pass through the holes **17***a* in the suction/insufflation tube **17** and leave the suction/insufflation tube **17** at its proximal end via port **38** as shown in FIG. **7**. Moisture removal from the ablation site may be further facilitated by the application of suction to the shaft **10** using the suction/insufflation unit **40**.

[0100] Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

[0101] Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

[0102] Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

[0103] Once the process has self terminated, 1-5 cc of saline can be introduced via suction/insufflation tube **17** and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction insufflation device **40** is then switched to provide insufflation of carbon dioxide at a pressure of 20-200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head **2** and to thus ease the closing of the RF applicator head. The RF applicator head **2** is moved to the closed position by sliding the handle **34** in a distal direction to fold the spring members **15**, **19** along the axis of the device and to cause the introducer sheath **32** to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor **56**. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment

Structure

[0104] A second embodiment of an ablation device **100** in accordance with the present invention is shown in FIGS. **21**-**37**B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

[0105] Referring to FIGS. **21** and **22**, the second embodiment includes an RF applicator head **102**, a sheath **104**, and a handle **106**. As with the first embodiment, the applicator head **102** is slidably disposed within the sheath **104** (FIG. **21**) during insertion of the device into the uterine cavity, and the handle **106** is subsequently manipulated to cause the applicator head **102** to extend from the distal end of the sheath **104** (FIG. **22**) and to expand into contact with body tissue (FIG. **33**).

[0106] RF Applicator Head

[0107] Referring to FIG. **23**, in which the sheath **104** is not shown for clarity, applicator head **102** extends from the distal end of a length of tubing **108** which is slidably disposed within the sheath **104**. Applicator head **102** includes an external electrode array **102***a* and an internal deflecting mechanism **102***b* used to expand and tension the array for positioning into contact with the tissue.

[0108] Referring to FIGS. **25**A and **25**B, the array **102***a* of applicator head **102** is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in FIGS. **26**A and **26**B) is formed of three monofilaments of nylon **109***a* knitted together with single yarns of spandex **19***b*. Each yarn of spandex **109***b* has a double helix **109***c* of five nylon monofilaments coiled around it.

[0109] This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

[0110] The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

[0111] Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially elongates from its coiled configuration.

[0112] One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere. Next, the insulating regions **110** (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface, is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

[0113] The mesh may be configured in a variety of shapes, including but not limited to the triangular shape **S1**, parabolic **S2**, and rectangular **S3** shapes shown in FIGS. **27**A, **27**B and **27**C, respectively.

[0114] Turning again to FIGS. **25**A and **25**B, when in its expanded state, the array **102***a* includes a pair of broad faces **112** spaced apart from one another. Narrower side faces **114** extend between the broad faces **112** along the sides of the applicator head **102**, and a distal face **116** extends between the broad faces **112** at the distal end of the applicator head **102**.

[0115] Insulating regions **110** are formed on the applicator head to divide the mesh into electrode regions. The insulated regions **110** are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

[0116] The array may be divided by the insulated regions **110** into a variety of electrode configurations. In a preferred configuration the insulating regions **110** divide the applicator head into four electrodes **118***a*-**118***d* by creating two electrodes on each of the broad faces **112**. To create this four-electrode pattern, insulating regions **110** are placed longitudinally along each of the broad faces **112** as well as along the length of each of the faces **114**, **116**. The electrodes **118***a*-**118***d* are used for ablation and, if desired, to measure tissue impedance during use.

[0117] Deflecting mechanism **102***b* and its deployment structure is enclosed within electrode array **102***a*. Referring to FIG. **23**, external hypotube **120** extends from tubing **108** and an internal hypotube **122** is slidably and co-axially disposed within hypotube **120**. Flexures **124** extend from the tubing **108** on opposite sides of external hypotube **120**. A plurality of longitudinally spaced apertures **126** (FIG. **28**) are formed in each flexure **124**. During use, apertures **126** allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube **120** using a vacuum source fluidly coupled to hypotube **120**.

[0118] Each flexure **124** preferably includes conductive regions that are electrically coupled to the array **102***a* for delivery of RF energy to the body tissue. Referring to FIG. **29**, strips **128** of copper tape or other conductive material extend along opposite surfaces of each flexure **124**. Each strip **128** is electrically insulated from the other strip **128** by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips **128** and extend through tubing **108** (FIG. **23**) to an electrical cord **130** (FIG. **21**) which is attachable to the RF generator.

[0119] During use, one strip **128** on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

[0120] The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures **124** may instead be used for electrically connecting the electrode array to the source of RF energy.

[0121] It is important to ensure proper alignment between the conductive regions of the flexures **124** (e.g. copper strips **128**) and the electrodes **118***a*-**118***d* in order to maintain electrical contact between the two. Strands of thread **134** (which may be nylon) (FIG. **23**) are preferably sewn through the array **102***a* and around the flexures **124** in order to prevent the conductive regions **128** from slipping out of alignment with the electrodes **118***a*-**118***d*. Alternate methods for maintaining contact between the array **102***a* and the conductive regions **128** include using tiny bendable barbs extending between the flexures **124** and the array **102***a* to hook the array to the conductive regions **128**, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

[0122] Referring again to FIG. **23**, internal flexures **136** extend laterally and longitudinally from the exterior surface of hypotube **122**. Each internal flexure **136** is connected at its

distal end to one of the flexures **124** and a transverse ribbon **138** extends between the distal portions of the internal flexures **136**. Transverse ribbon **138** is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in FIG. **23** and such that when in a compressed condition it is folded along the plurality of creases **140** that extend along its length. Flexures **124**, **136** and ribbon **138** are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

[0123] The deflecting mechanism is preferably configured such that the distal tips of the flexures **124** are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections **124***a* (FIG. **28**) of the flexures from a material that is more flexible than the proximal sections **124***b*. For example, flexures **124** may be provided to have proximal sections formed of a material having a modulus of approximately 28×106 psi and distal sections having a durometer of approximately 72D.

[0124] Alternatively, referring to FIG. **30**, the flexures **124** may be joined to the internal flexures **136** at a location more proximal than the distal tips of the flexures **124**, allowing them to move more freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in FIG. **30**). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

[0125] The deflecting mechanism formed by the flexures **124**, **136**, and ribbon **138** forms the array into the substantially triangular shape shown in FIG. **23**, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips **142**, **144** forming handle **106** are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube **120** and relative forward motion of the hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deploys and tensions the electrode array **102***a*.

[0126] Measurement Device

[0127] The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge **146** (FIG. **21**). The measurement device utilizes non-conductive (e.g. nylon) suturing threads **148** that extend from the hypotube **122** and that have distal ends attached to the distal portion of the deflecting mechanism (FIG. **23**). As shown in FIG. **24**, threads **148** are preferably formed of a single strand **150** threaded through a wire loop **152** and folded over on itself. Wire loop **152** forms the distal end of an elongate wire **154** which may be formed of stainless steel or other wire.

[0128] Referring to FIG. **31**, wire **154** extends through the hypotube **122** and is secured to a rotatable bobbin **156**. The rotatable bobbin **156** includes a dial face **158** preferably covered in a clear plastic. As can be seen in FIG. **32***b*, dial face **158** includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing **160** and a corresponding marker line **162** is printed on the gauge housing. A torsion spring **164** provides rotational resistance to the bobbin **156**.

[0129] Expansion of the applicator head **102** during use pulls threads **148** (FIG. **23**) and thus wire **154** (FIG. **24**) in a distal direction. Wire **154** pulls against the bobbin **156** (FIG. **31**), causing it to rotate. Rotation of the bobbin positions one of the calibration markings on dial face **158** into alignment with the marker line **162** (FIG. **32**B) to indicate the distance between the distal tips of flexures **124** and thus the uterine width.

[0130] The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

[0131] The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures **124** and to electronically transmit the uterine width to the RF generator.

[0132] Control of Ablation Depth

[0133] The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2-3 mm for the cervical os and the cornual regions, and approximately 7-8 mm in the main body of the uterus where the endometrium is substantially thicker.

[0134] As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

[0135] Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can been seen with reference to FIG. **33** that the center to center distance d**1** between the electrodes **118***a*, **118***b* is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d**2** between electrodes **118***a*, **118***b* is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d**3** extend between top and bottom electrodes **118***b*, **118***c* and **118***a*, **118***d* and again contribute to shallower ablation.

[0136] Naturally, because the array **102***a* expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array **102***a* vary. One embodiment of the array **102***a* includes a range of widths of at least approximately 2.5-4.5 cm, a range of lengths of at least approximately 4-6 cm, and a density of approximately 35%-45%.

[0137] The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head **102** and displayed on gauge **146**. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

[0138] The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following relationship:

$$P=L\times W\times 5.5$$

[0139] Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

[0140] Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

[0141] Handle

[0142] Referring again to FIGS. **21** and **22**, the handle **106** of the RF ablation device according to the second embodiment includes a distal grip section **142** and a proximal grip section **144** that are pivotally attached to one another at pivot pin **166**.

[0143] The proximal grip section **144** is coupled to the hypotube **122** (FIG. **23**) via yoke **168**, overload spring **170** and spring stop **172**, each of which is shown in the section view of FIG. **34**. The distal grip section **142** is coupled to the external hypotube **120** via male and female couplers **174**, **176** (see FIGS. **32**A and **32**B). Squeezing the grip sections **142**, **144** towards one another thus causes relative movement between the external hypotube **120** and the internal hypotube **122**. This relative sliding movement results in deployment of the deflecting mechanism **102***b* from the distal end of the sheath and expansion of the array **102***a* to its expanded state.

[0144] Referring to FIGS. **32**A and B, rack **180** is formed on male coupler **174** and calibration markings **182** are printed adjacent the rack **180**. The calibration markings **182** correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

[0145] A sliding collar **184** is slidably disposed on the tubing **108** and is slidable over male coupler **174**. Sliding collar **184** includes a rotating collar **186** and a female coupler **176** that includes a wedge-shaped heel **188**. A locking spring member **190** (FIGS. **32**B and **35**) extends across an aperture **192** formed in the proximal grip **144** in alignment with the heel **188**. When the distal and proximal handle sections are squeezed together to deploy the array, the heel **188** passes into the aperture **192**. Its inclined lower surface gradually depresses the spring member **190** as the heel moves further into the aperture **192**. See FIGS. **36**A and **36**B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See FIG. **36**C.

[0146] A release lever **194** (FIG. **35**) is attached to the free end of the spring member **190**. To disengage the spring lock, release lever **194** is depressed to lower spring member **190** so that the inclined heel can pass over the spring member and thus out of the aperture **192**.

[0147] Referring again to FIGS. **32**A and **32**B, sliding collar **184** is configured to allow the user to limit longitudinal extension of the array **102***a* to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler **174** relative to the female coupler **176** using the rotating collar **186** to lock and unlock the female coupler from the rack **180** and the male coupler **174**. Locking the female coupler to the rack **180** and male coupler **174** will limit extension of the array to approximately the predetermined uterine length, as shown on the calibration markings **182**.

[0148] Once the uterine length has been measured using a conventional sound, the user positions sliding collar **184** adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section **186** to engage its internally positioned teeth with the rack **180**. This locks the longitudinal position of the heel **188** such that it will engage with the spring member **190** on the proximal grip when the array has been exposed to the length set by the sliding collar.

[0149] The handle **106** includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array **102***a*. One of the spring assemblies controls movement of the grips **142**, **144** to automatically stow the array **102***a* into the sheath **104** when the user stops squeezing the grips **142**, **144** towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures **124** to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism **102***b*.

[0150] FIG. **34** shows the distal and proximal grips **142** and **144** in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel **196** that is slidably disposed within the proximal grip **144**. A compression spring **198** surrounds a portion of the return mandrel **196**, and a retaining ring **200** is attached to the mandrel **196** above the spring **198**. A spring stop **202** is disposed between the spring **198** and the retaining ring.

[0151] The lowermost end of the return mandrel **196** is pivotally engaged by a coupling member **204** on distal grip **142**. Relative movement of the grips **142**, **144** towards one another causes the coupling member **204** to pull the return member downwardly with the proximal grip **144** as indicated by arrows. Downward movement of the mandrel **196** causes its retaining ring **200** and spring stop **202** to bear downwardly against the compression spring **198**, thereby providing a movement which acts to rotate the grips **142**, **144** away from one another. When tension against the grips **142**, **144** is released (assuming that heel **188** is not locked into engagement with spring member **190**) the grips rotate apart into the opened position as the compression spring **198** returns to the initial state, stowing the applicator head inside the sheath.

[0152] The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member **178** disposed over yoke **168**, Which is pivotally attached to proximal grip **144**. Tubing **108** extends from the array **102***a* (see FIG. **23**), through the sheath

104 and is fixed at its proximal end to the frame member **178**. Hypotube **122** does not terminate at this point but instead extends beyond the proximal end of tubing **108** and through a window **206** in the frame member. Its proximal end **208** is slidably located within frame member **178** proximally of the window **206** and is fluidly coupled to a vacuum port **210** by fluid channel **212**. Hypotube **120** terminates within the frame. Its proximal end is fixed within the distal end of the frame.

[0153] A spring stop **172** is fixed to a section of the hypotube within the window **206**, and a compression spring **170** is disposed around the hypotube between the spring stop **172** and yoke **168**. See FIGS. **32**B and **34**.

[0154] When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath **104** from the array **102***a*. Referring to FIGS. **37**A and **37**B, this motion continues until female coupler **176** contacts and bears against frame member **178**. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube **120**. An opposing force is developed in yoke **168**, which causes a relative forward motion in hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deflect in a manner that deploys and tensions the electrode array. Compression spring **170** acts to limit the force developed by the operator against hypotubes **120**, **122**, thus limiting the force of flexures **124**, **136** acting on the array and the target tissue surrounding the array.

[0155] Referring to FIG. **21**, collar **214** is slidably mounted on sheath **104**. Before the device is inserted into the uterus, collar **214** can be positioned along sheath **104** to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head **102** has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar **214** can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

Second Exemplary Embodiment

Operation

[0156] In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar **184** (FIG. **32**B) adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section **186** to engage its internally positioned teeth with the rack **180**. This locks the longitudinal position of the heel **188** (FIG. **32**A) such that it will engage with the spring member **190** when the array has been exposed to the length set by the sliding collar.

[0157] Next, with the grips **142**, **144** in their resting positions to keep the applicator head **102** covered by sheath **104**, the distal end of the device **100** is inserted into the uterus. Once the distal end of the sheath **104** is within the uterus, grips **142**, **144** are squeezed together to deploy the applicator head **102** from sheath **104**. Grips **142**, **144** are squeezed until heel **188** engages with locking spring member **190** as described with respect to FIGS. **3**BA through **36**C.

[0158] At this point, deflecting mechanism **102***b* has deployed the array **102***a* into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge **146**. The measured length and width are entered into the RF generator system **250** (FIG. **21**) and used to calculate the ablation power.

[0159] Vacuum source **252** (FIG. **21**) is activated, causing application of suction to hypotube **122** via suction port **210**. Suction helps to draw uterine tissue into contact with the array **102**.

[0160] Ablation power is supplied to the electrode array **102***a* by the RF generator system **250**. The tissue is heated as the RF energy passes from electrodes **118***a-d* to the tissue, causing moisture to be released from the tissue. The vacuum source **252** helps to draw moisture from the uterine cavity into the hypotube **122**. Moisture withdrawal is facilitated by the apertures **126** formed in flexures **124** by preventing moisture from being trapped between the flexures **124** and the lateral walls of the uterus.

[0161] If the RF generator **250** includes an impedance monitoring module, impedance may be monitored at the electrodes **118***a-d* and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

[0162] When RF delivery is terminated, the user depresses release lever **194** to disengage heel **188** from locking spring member **190** and to thereby allow grips **142**, **144** to move to their expanded (resting) condition. Release of grips **142**, **144** causes applicator head **102** to retract to its unexpanded condition and further causes applicator head **102** to be withdrawn into the sheath **104**. Finally, the distal end of the device **100** is withdrawn from the uterus.

[0163] Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

1-7. (canceled)

8. A device for treating a uterus comprising:

an elongate member having a proximal end and a distal end, the elongate member including a translatable sleeve;

an applicator head coupled to the distal end, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus;

a deflecting mechanism including flexures disposed within the applicator head and a translatable sleeve operably coupled to the flexures, wherein the deflecting mechanism is configured so that translating the translatable sleeve causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the translatable sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

9. The device of claim **8** wherein the deflector mechanism further comprises a secondary sleeve, and wherein relative motion between the translatable sleeve and the secondary sleeve causes the applicator head to transition from the contracted state to the expanded state.

10. The device of claim **8** wherein the indicator mechanism indicates a distance between the flexures when the applicator head is in an expanded state.

11. The device of claim **8** wherein the applicator head is configured to ablate the uterus.

12. The device of claim **8** wherein the applicator head is configured to deliver radio-frequency energy.

13. The device of claim **8** further comprising a transverse ribbon coupled to a distal end of the flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state.

14. The device of claim **8** wherein the flexures include a plurality of longitudinally spaced apertures.

15. A device for treating a uterus comprising:

an elongate member having a proximal end and a distal end;

an applicator head coupled to the distal end of the elongate member, the applicator head defined by deformable walls having an expanded state and a contracted state, the expanded state being configured to conform to the shape of the uterus and the contracted state being configured for transcervical insertion;

a deflecting mechanism disposed within the applicator head and configured expand the applicator head from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the deflecting mechanism, the indicator mechanism configured to indicate a dimension of the uterus.

16. The device of claim **15** wherein the deflecting mechanism includes a plurality of flexures having distal tips, and wherein the indicator mechanism is configured to indicate a distance between the distal tips.

17. The device of claim **15** wherein the elongate member includes an internal hypotube and an external hypotube, wherein the internal hypotube is disposed within the external hypotube, and wherein relative movement between the internal hypotube and the external hypotube deploys the deflecting mechanism and causes the applicator head to transition from the contracted state to the expanded state.

18. The device of claim **17** wherein a distance of relative movement between the internal hypotube and the external hypotube is indicative of a dimension of the uterus.

* * * * *

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Truckai et al.

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(54) **METHOD FOR ABLATING AND/OR COAGULATING TISSUE USING MOISTURE TRANSPORT**

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(58) **Field of Search** 607/100, 101, 607/108, 96, 98, 99, 1, 2, 115, 116, 27, 32, 122, 138; 600/372, 373, 377, 591; 604/20, 21, 22, 28, 48, 500, 506, 514, 515, 517, 93.01, 264, 275, 113, 114, 49, 55, 95.01–96.01, 35, 511, 509; 606/47, 119, 191, 193, 198

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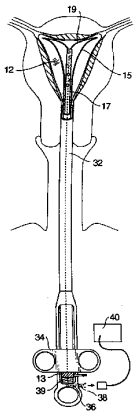
(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. The array includes conductive regions separated by insulated regions arranged to produce ablation to a predetermined depth. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

47 Claims, 18 Drawing Sheets



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Next, with the grips **142**, **144** in their resting positions to keep the applicator head **102** covered by sheath **104**, the distal end of the device **100** is inserted into the uterus. Once the distal end of the sheath **104** is within the uterus, grips **142**, **144** are squeezed together to deploy the applicator head **102** from sheath **104**. Grips **142**, **144** are squeezed until heel **188** engages with locking spring member **190** as described with respect to FIGS. **36**A through **36**C.

At this point, deflecting mechanism **102***b* has deployed the array **102***a* into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge **146**. The measured length and width are entered into the RF generator system **250** (FIG. **21**) and used to calculate the ablation power.

Vacuum source **252** (FIG. **21**) is activated, causing application of suction to hypotube **122** via suction port **210**. Suction helps to draw uterine tissue into contact with the array **102**.

Ablation power is supplied to the electrode array **102***a* by the RF generator system **250**. The tissue is heated as the RF energy passes from electrodes **118***a–d* to the tissue, causing moisture to be released from the tissue. The vacuum source helps to draw moisture from the uterine cavity into the hypotube **122**. Moisture withdrawal is facilitated by the apertures **126** formed in flexures **124** by preventing moisture from being trapped between the flexures **124** and the lateral walls of the uterus.

If the RF generator **250** includes an impedance monitoring module, impedance may be monitored at the electrodes **118***a–d* and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever **194** to disengage heel **188** from locking spring member **190** and to thereby allow grips **142**, **144** to move to their expanded (resting condition). Release of grips **142**, **144** causes applicator head **102** to retract to its unexpanded condition and further causes applicator head **102** to be withdrawn into the sheath **104**. Finally, the distal end of the device **100** is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

We claim:

1. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the fluid permeable elastic member includes metallized fabric;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

2. The method of claim **1** wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

3. The method of claim **2** wherein the metallized fabric includes yarns of spandex and nylon.

4. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into an organ and into contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering RF energy through the array to the tissue at approximately the selected power to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

5. The method of claim **4** wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

6. The method of claim **5** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

7. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

8. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the fluid permeable elastic member includes metallized fabric;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

9. The method of claim **8** wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

10. The method of claim **9** wherein the metallized fabric includes yarns of spandex and nylon.

11. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array within an organ and into contact with tissue to be ablated;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering RF energy through the array to the tissue at approximately the selected power to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

12. The method of claim **11** wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

13. The method of claim **12** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

14. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

15. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the fluid permeable elastic member includes metallized fabric;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, and applying suction to draw the moisture through the tubular member.

16. The method of claim **15** wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

17. The method of claim **16** wherein the metallized fabric includes yarns of spandex and nylon.

18. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into and organ and contact with tissue to be ablated and moving the array to an expanded condition;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering RF energy to the tissue at approximately the selected power to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, and applying suction to draw the moisture through the tubular member.

19. The method of claim **18** wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

20. The method of claim **19** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

21. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, and applying suction to draw the moisture through the tubular member.

22. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array within an organ and into contact with tissue to be ablated;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering the RF energy to the tissue at approximately the selected power to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

23. The method of claim **22** wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the organ from the relative positions of the flexures in the expanded condition.

24. The method of claim **22** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

25. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member including metallized fabric having insulating regions and conductive regions thereon, the metallized fabric including yarns of elastic material and yarns of inelastic material;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

26. The method of claim **25** wherein the metallized fabric includes yarns of spandex and nylon.

27. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

28. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable bipolar electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array comprising a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

29. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including a bipolar electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RE energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

30. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable bipolar electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction to the tubular member and through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, the suction drawing the moisture through the tubular member.

31. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an bipolar electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

32. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures, the suction substantially eliminating liquid surrounding the electrodes during ablation.

33. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member the suction substantially eliminating liquid surrounding the electrodes during ablation.

34. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction to the tubular member and through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, the suction drawing the moisture through the tubular member, the suction substantially eliminating liquid surrounding the electrodes during ablation.

35. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array, the suction substantially eliminating liquid surrounding the electrodes during ablation.

36. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures, wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

37. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member and wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

38. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction to the tubular member and through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, the suction drawing the moisture through the tubular member, and wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

39. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array and wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

40. The method of claim **28**, **29**, **30**, **36**, **37**, **38** or **39**, wherein the suction draws tissue into contact with the electrode carrying member.

41. The method of claim **40** wherein the tissue is inside an organ, and wherein the suction at least partially collapses the organ onto the electrode carrying member.

42. The method of claim **28**, **29**, **30**, **31**, **36**, **37**, **38** or **39**, wherein the tissue is within a uterus, wherein the positioning step passes the electrode array through the cervix and into the uterus, and wherein the method further includes forming a seal around the elongate tubular member at the cervix.

43. The method of claim **28**, **29**, **30**, **31**, **36**, **37**, **38** or **39** wherein the fluid permeable elastic member includes metallized filaments.

44. The method of claim **43** wherein the metallized filaments include elastic and inelastic filaments.

45. The method of claim **44** wherein the metallized filaments include filaments of spandex and nylon.

46. The method of claim **28**, **29**, **30**, **31**, **36**, **37**, **38** or **39** wherein said suction substantially preventing formation of a low-impedance liquid layer around the electrode array during ablation/coagulation using the electrode array.

47. The method of claim **28**, **29**, **30** or **31** wherein substantially the entire bipolar electrode array maintains continuous contact with the tissue to be ablated during said ablation and/or coagulation of the tissue.

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(12) **United States Patent**
Truckai et al.

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(54) **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 149 days.

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(Continued)

(58) **Field of Classification Search**
CPC A61B 2018/00577; A61B 2018/00449; A61B 2018/00559
USPC 606/41; 607/101, 105, 138
See application file for complete search history.

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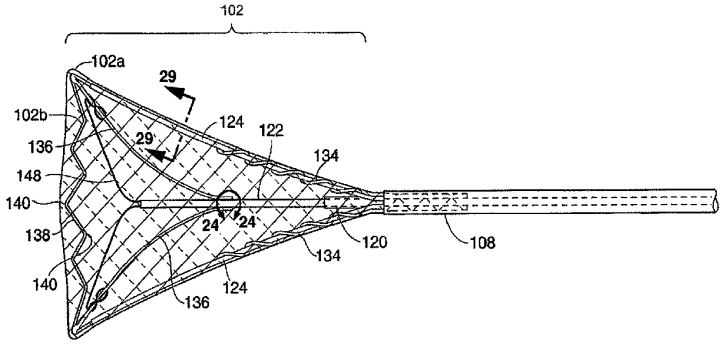
(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

15 Claims, 18 Drawing Sheets



Related U.S. Application Data

division of application No. 09/103,072, filed on Jun. 23, 1998, now Pat. No. 6,813,520.

(60) Provisional application No. 60/084,791, filed on May 8, 1998.

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A61B 19/00	(2006.01)

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CPC ***A61B18/18*** (2013.01); ***A61B 19/40*** (2013.01); ***A61M 16/0481*** (2014.02); *A61B 2017/22051* (2013.01); *A61B 2017/4216* (2013.01); *A61B 2018/00291* (2013.01); *A61B 2018/00559* (2013.01); *A61B 2018/00577* (2013.01); *A61B 2018/00708* (2013.01); *A61B 2018/126* (2013.01); *A61B 2019/4009* (2013.01); *A61B 2019/465* (2013.01)

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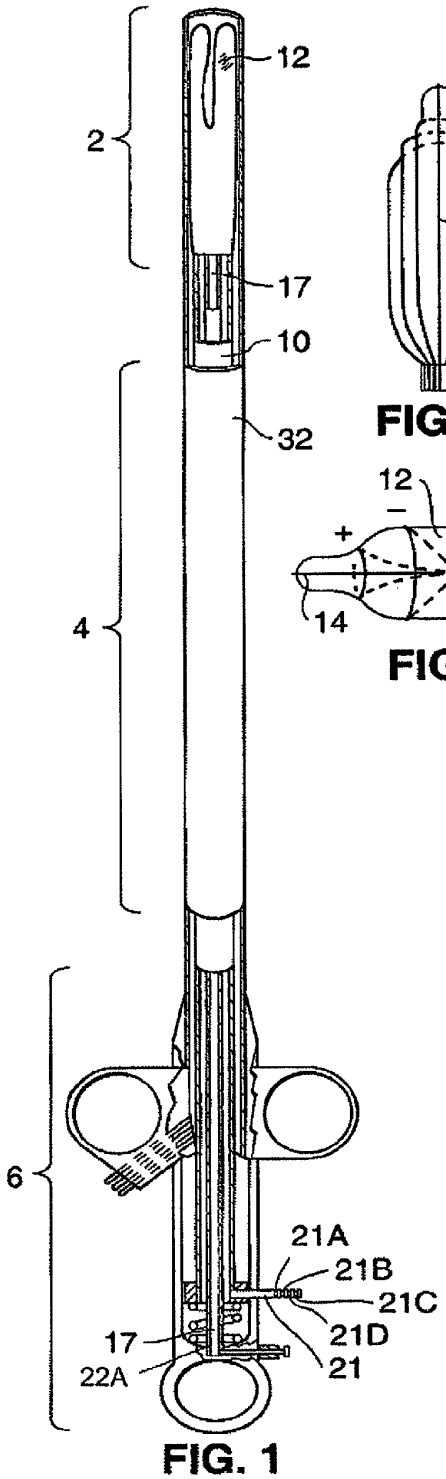


FIG. 1

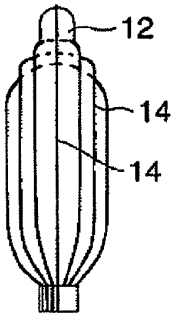


FIG. 3

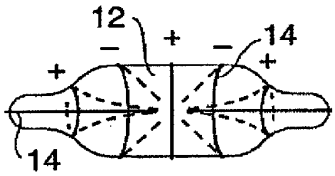


FIG. 4

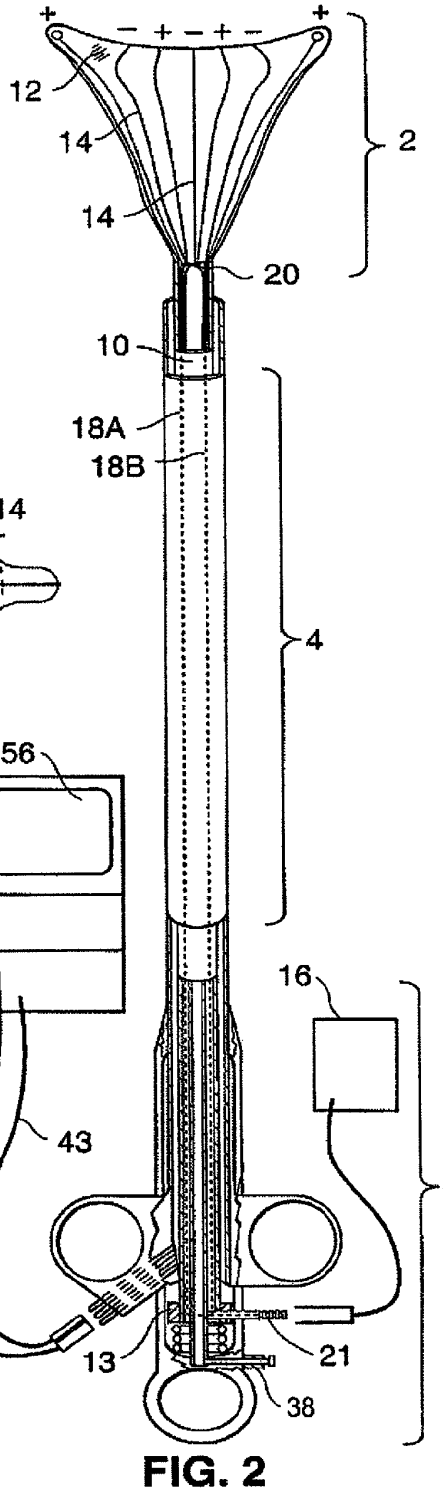
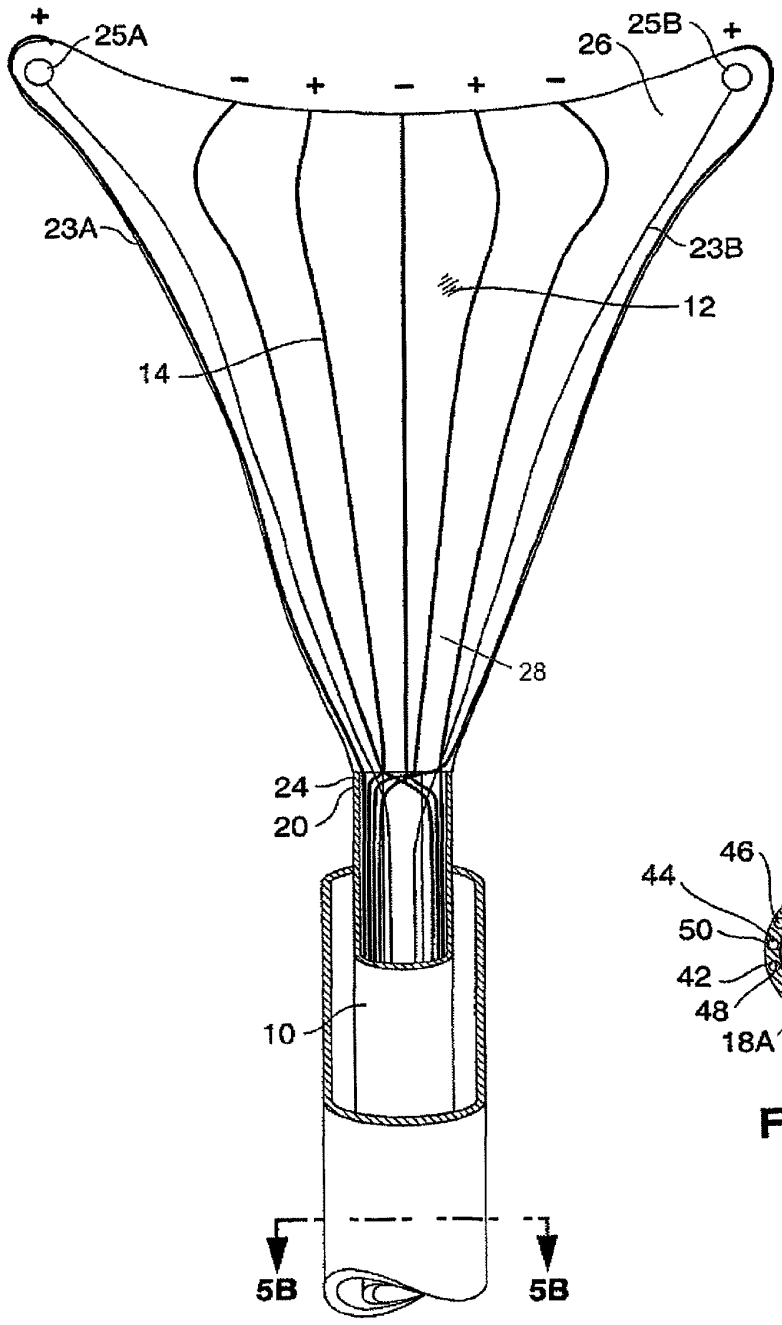


FIG. 2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25B
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26
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23A
23B
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14
28
24
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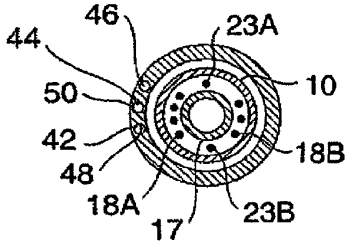
10
5B
5B

FIG. 5A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23B
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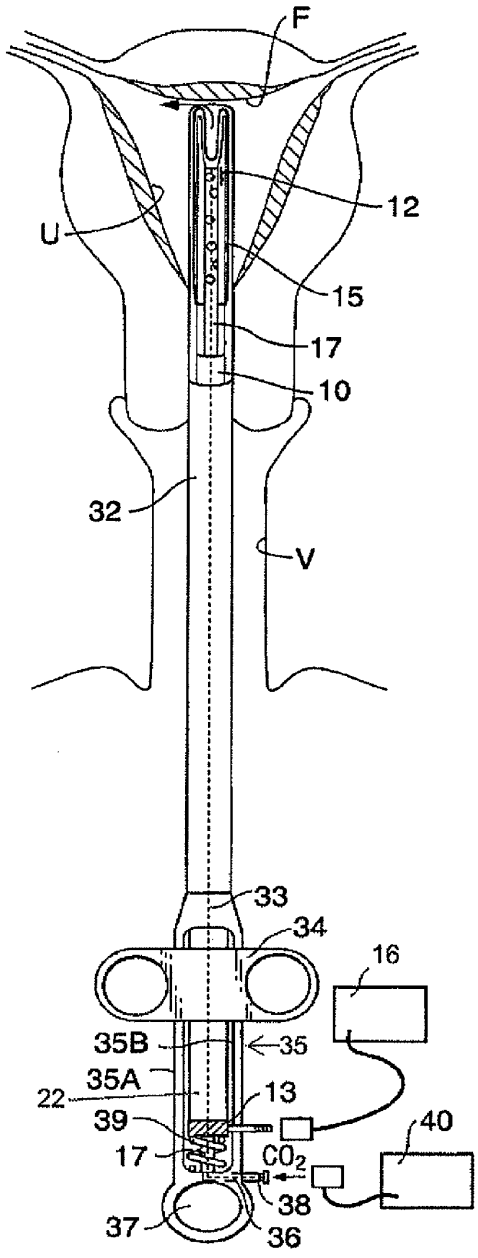
FIG. 5B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CO_2
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36

FIG. 6

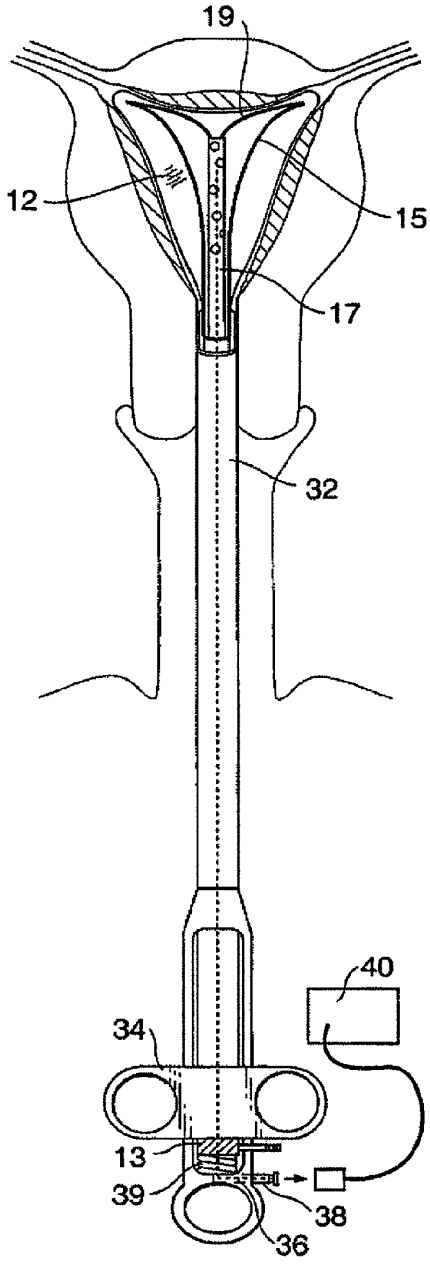
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FIG. 7

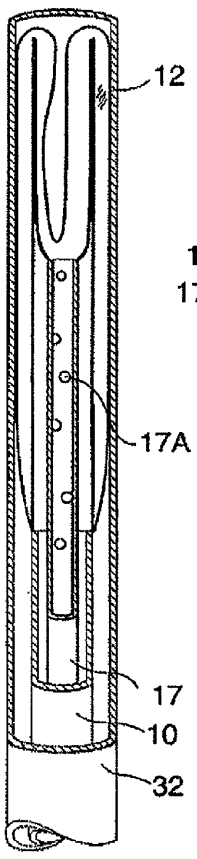

FIG. 8

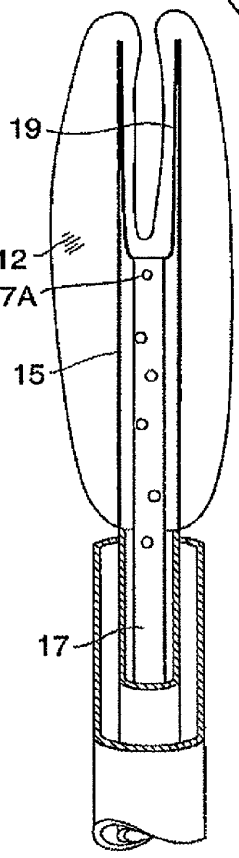

FIG. 9

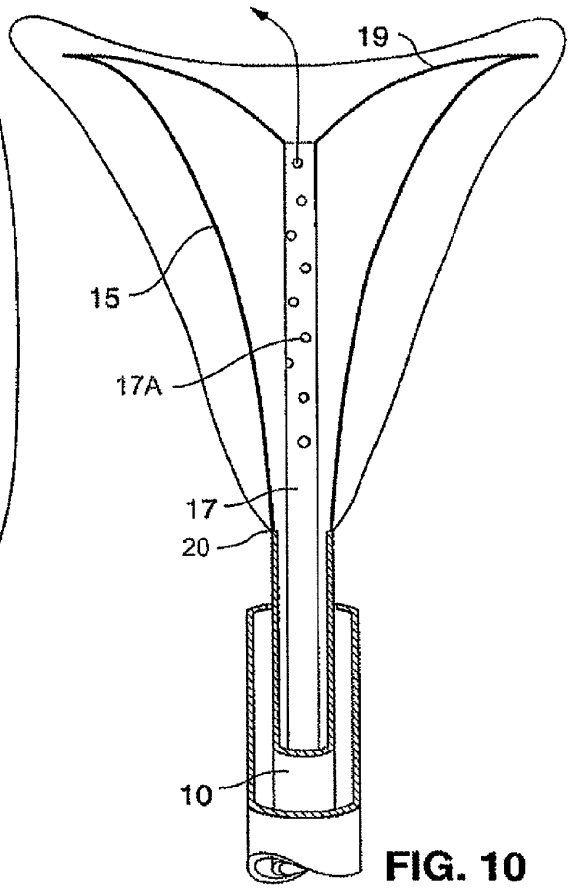

FIG. 10

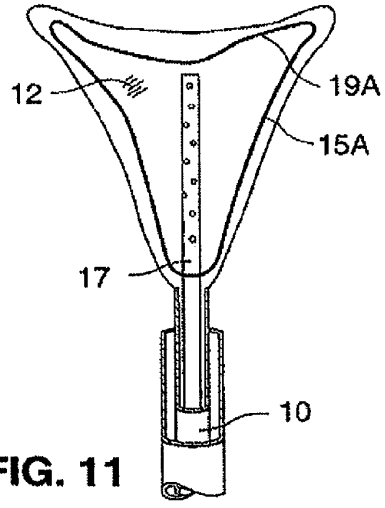

FIG. 11

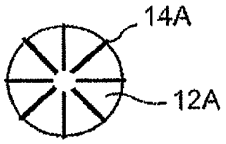

FIG. 13

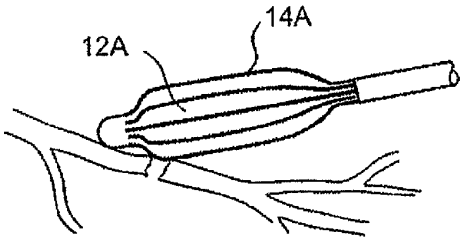

FIG. 14

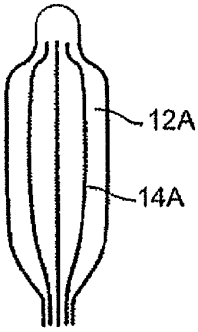

FIG. 12

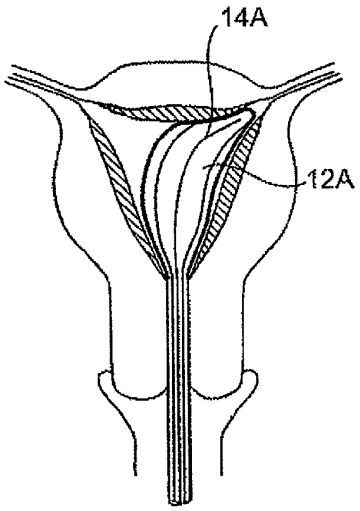

FIG. 15

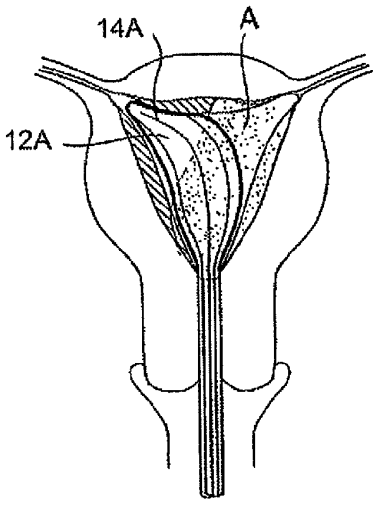

FIG. 16

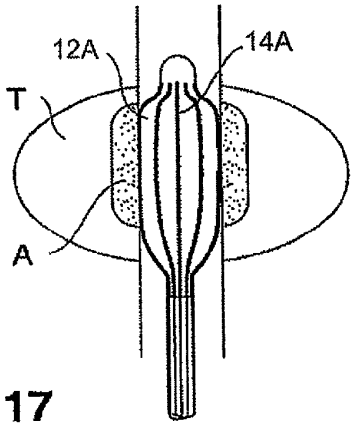

FIG. 17

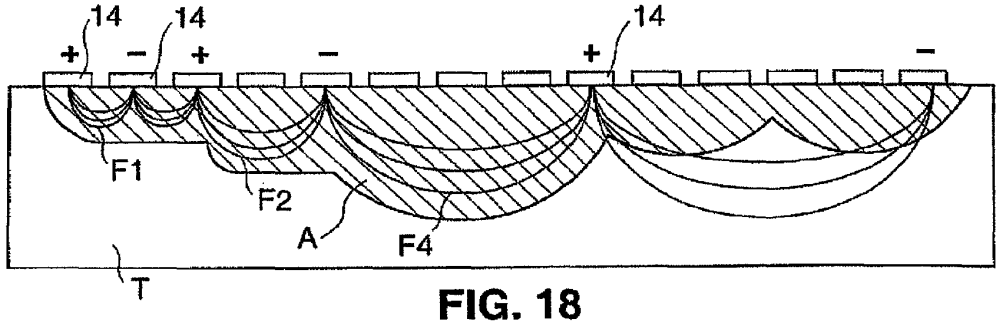

FIG. 18

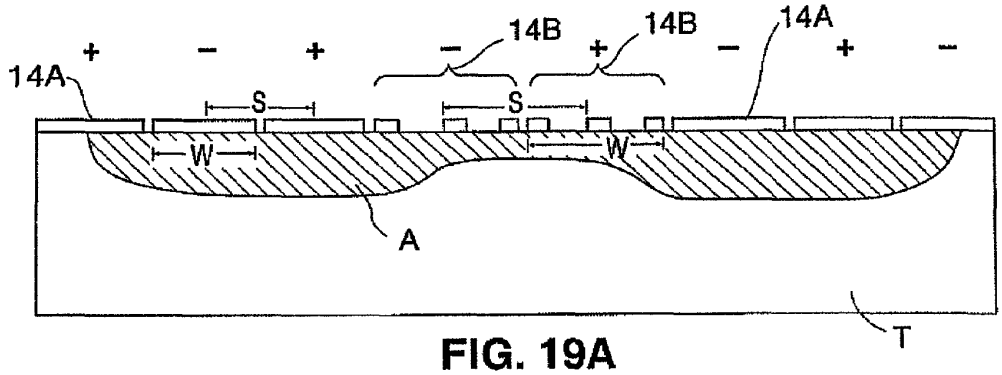

FIG. 19A

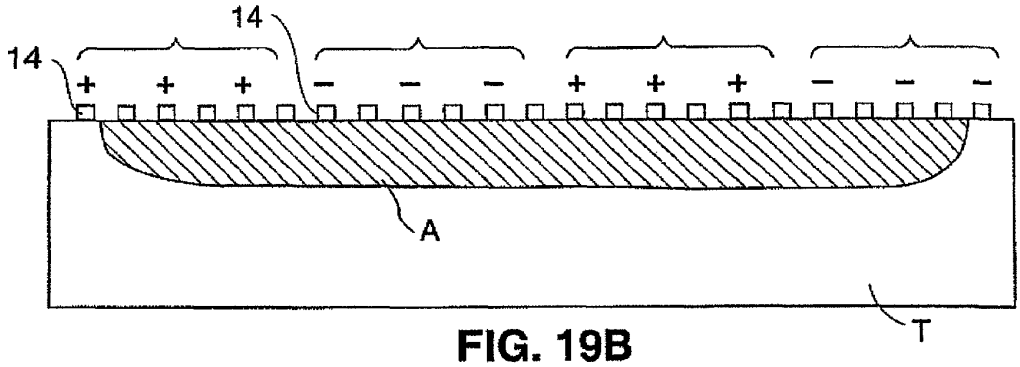

FIG. 19B

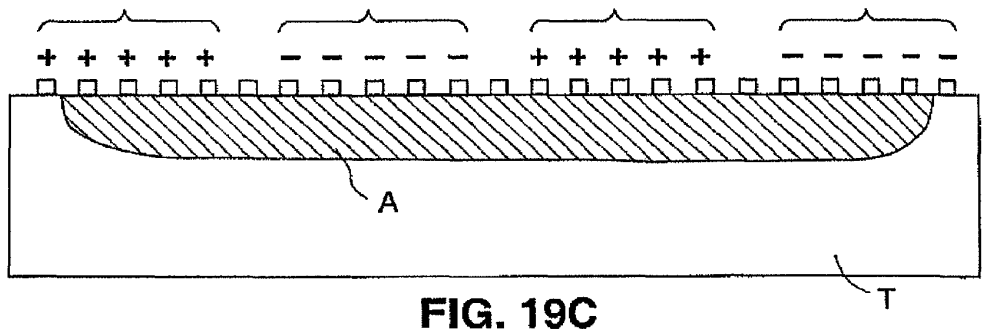

FIG. 19C

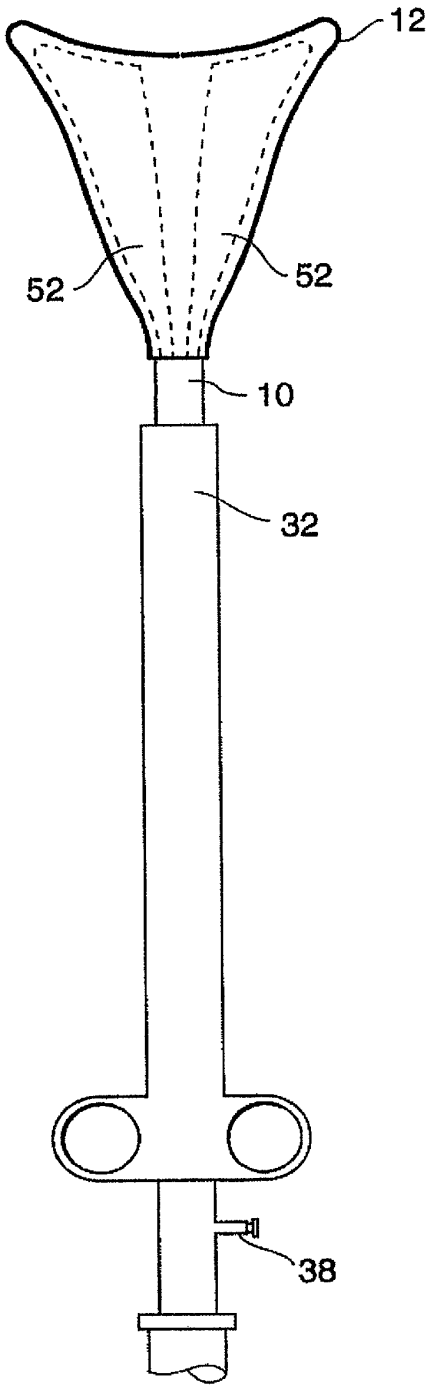

FIG. 20

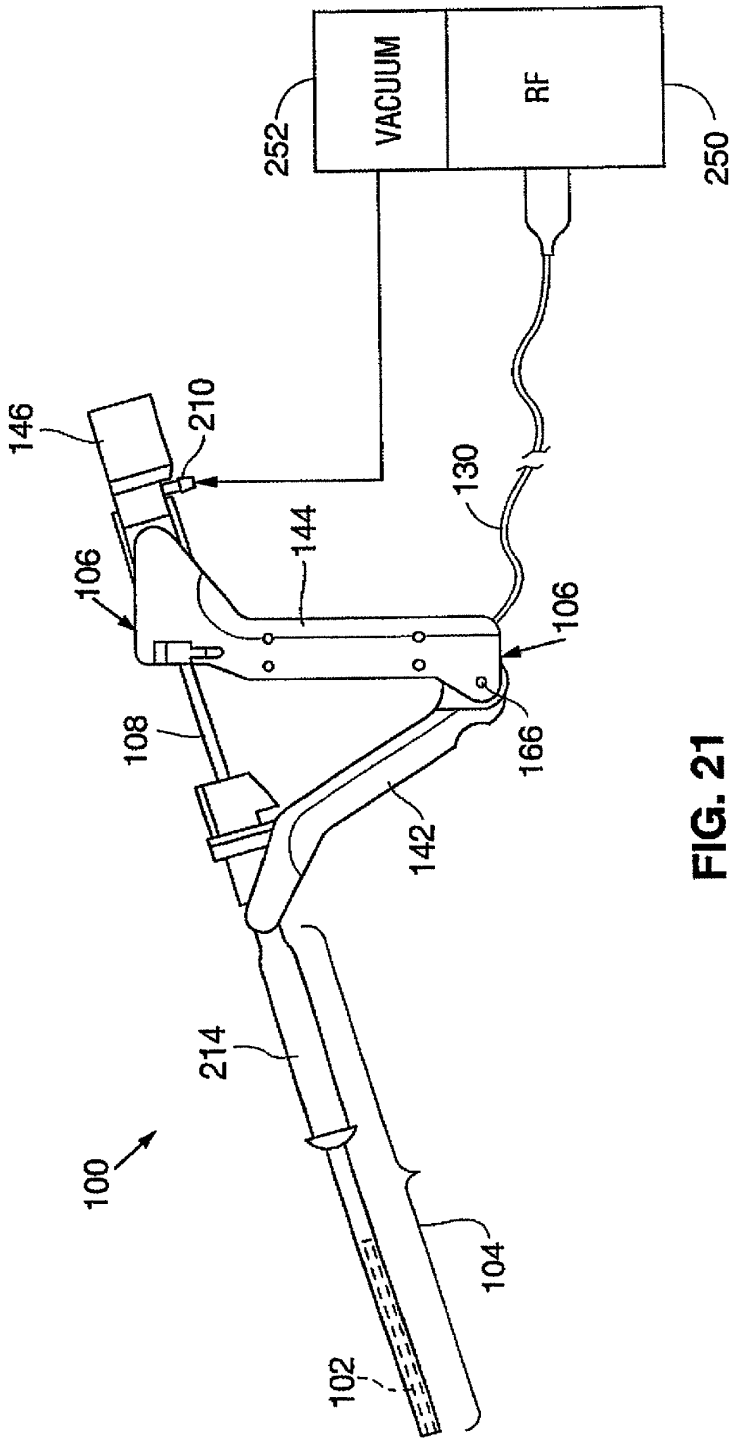

FIG. 21

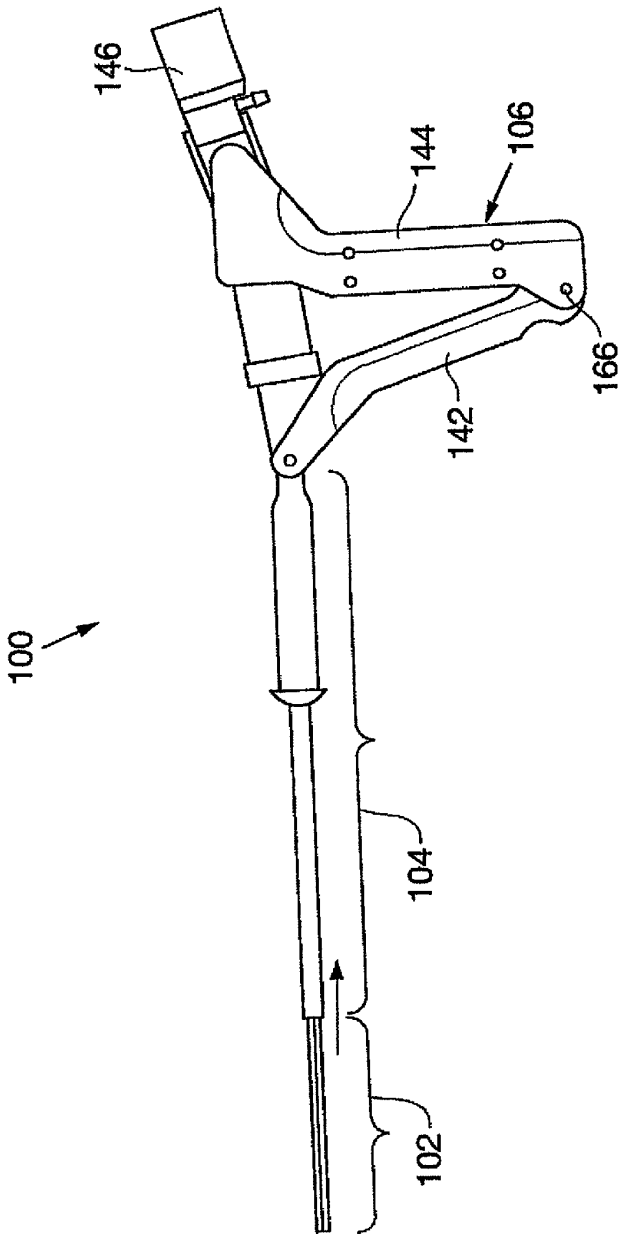

FIG. 22

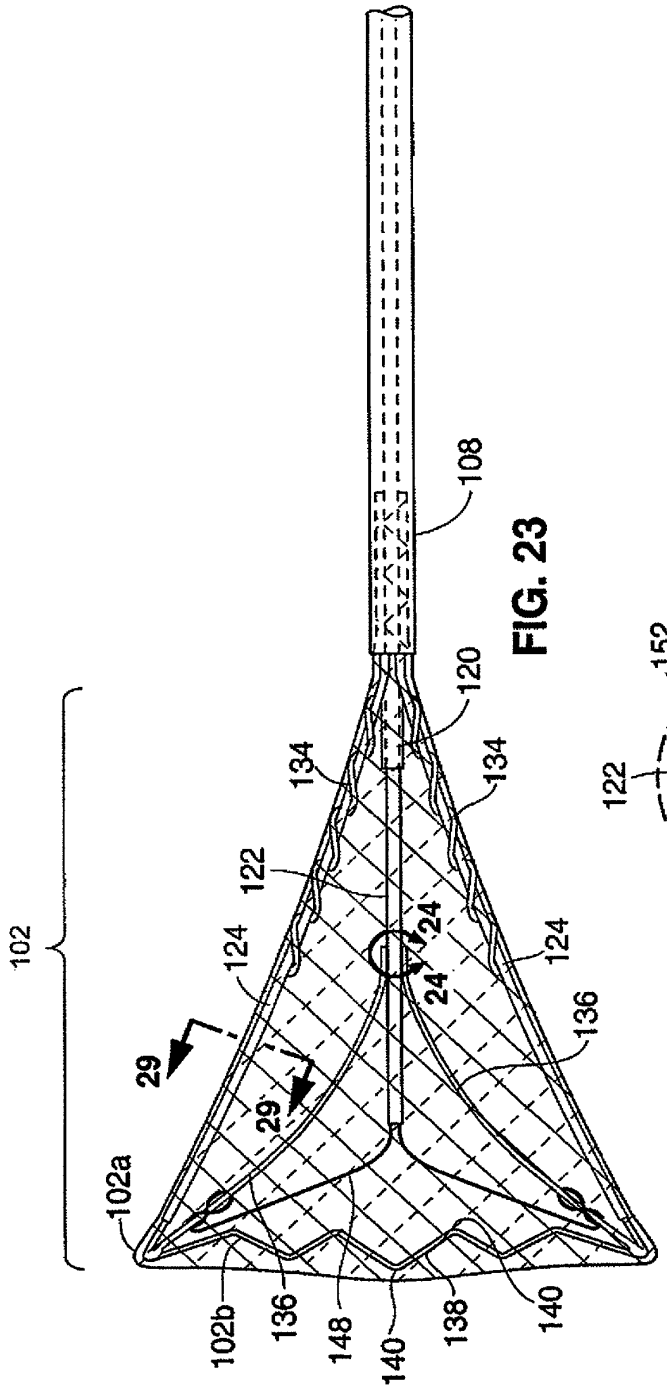

FIG. 23

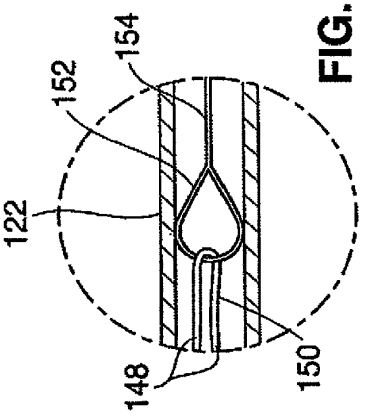

FIG. 24

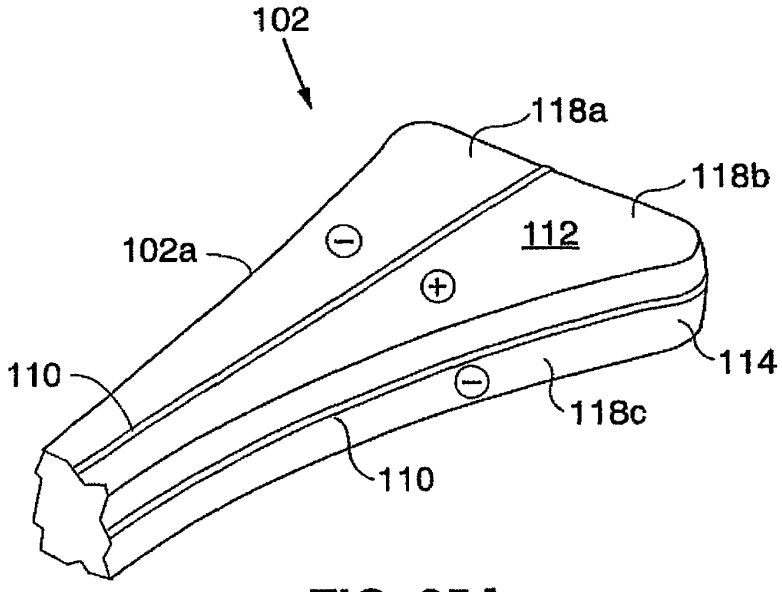

FIG. 25A

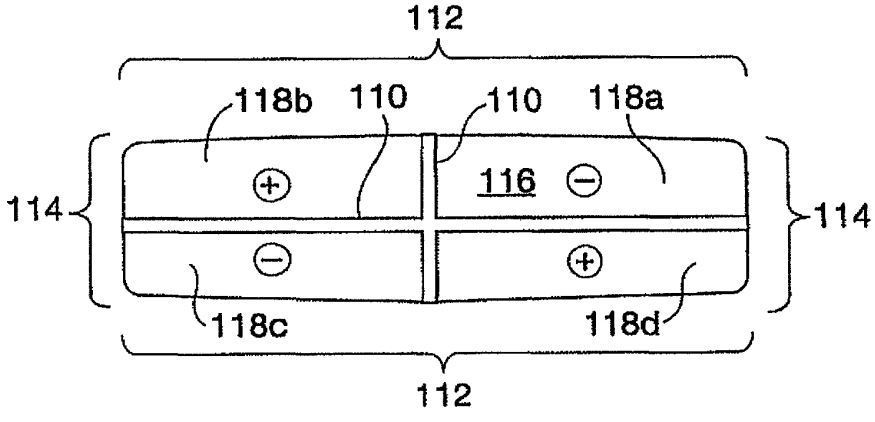

FIG. 25B

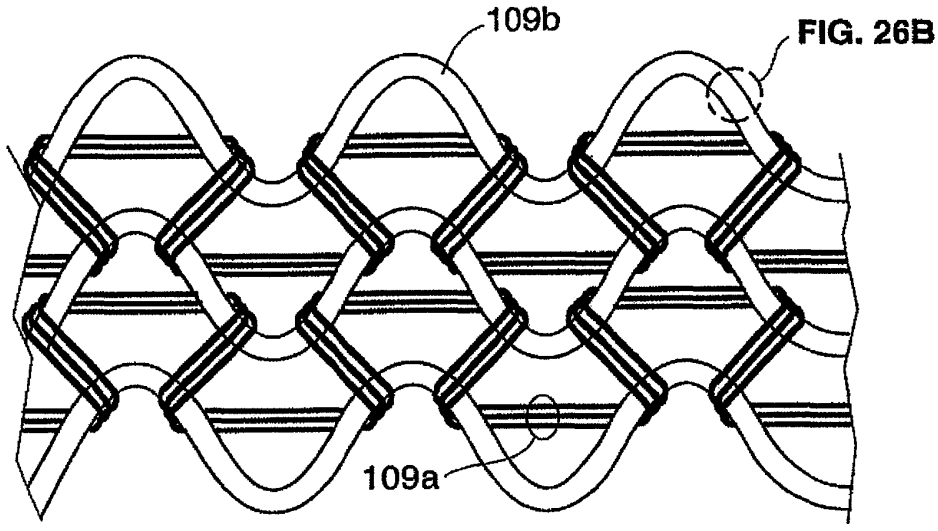

FIG. 26A

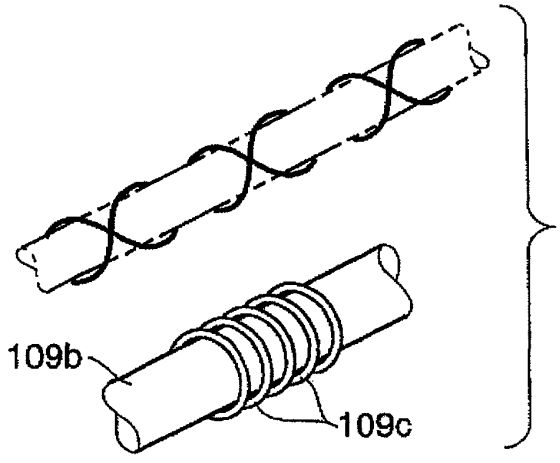

FIG. 26B

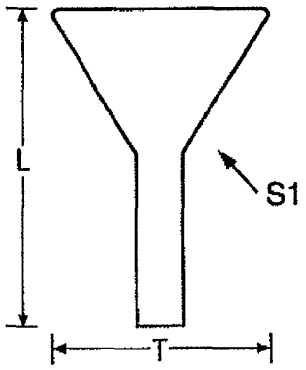

FIG. 27A

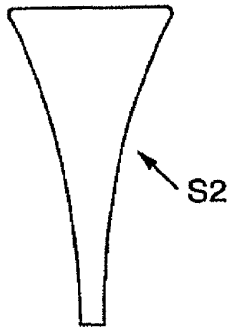

FIG. 27B

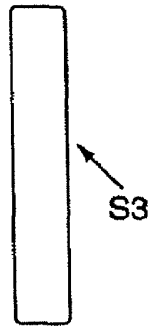

FIG. 27C

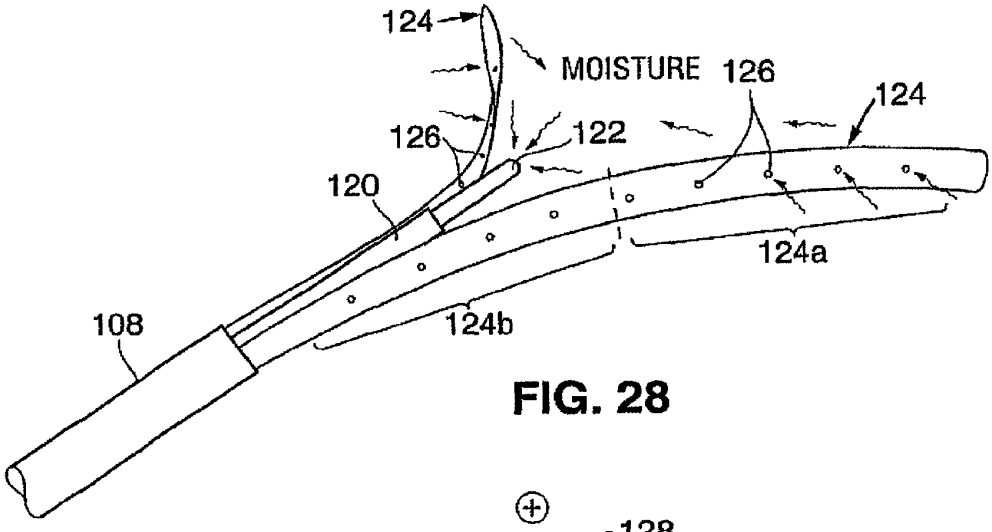

FIG. 28

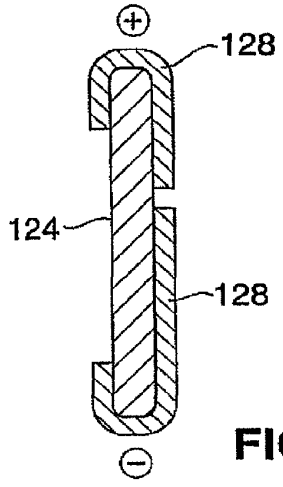

FIG. 29

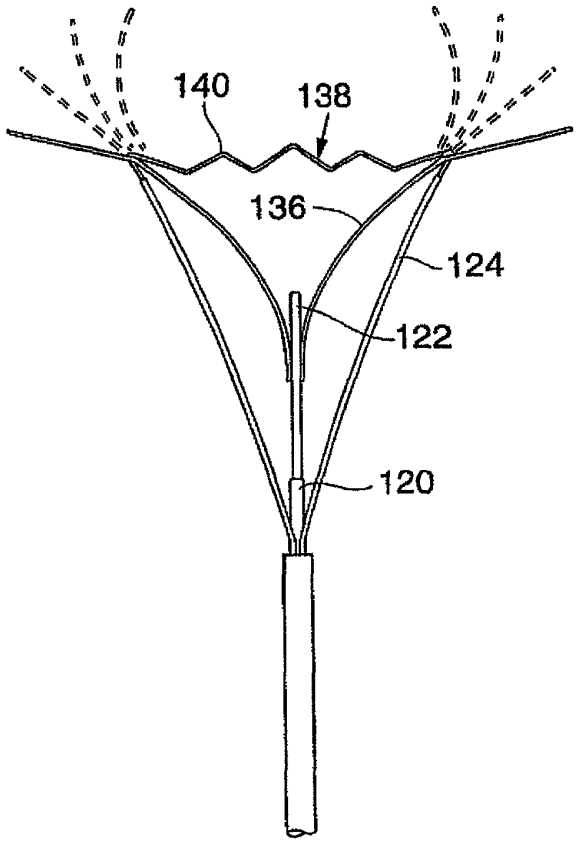

FIG. 30

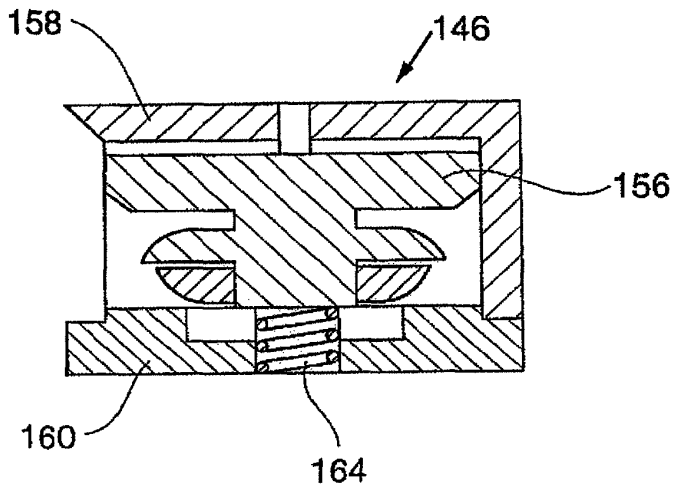

FIG. 31

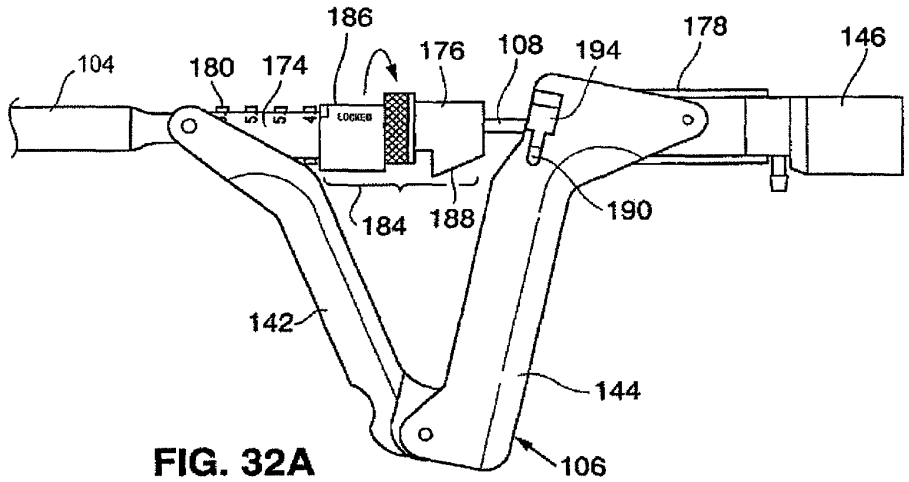

FIG. 32A

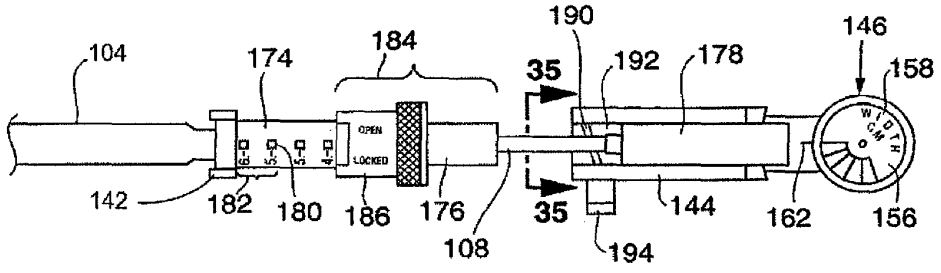

FIG. 32B

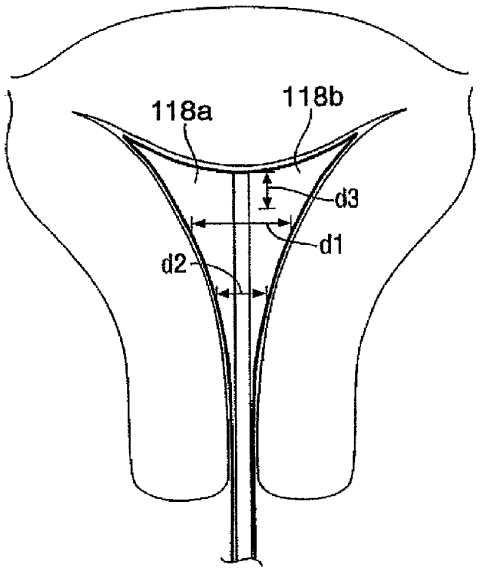

FIG. 33

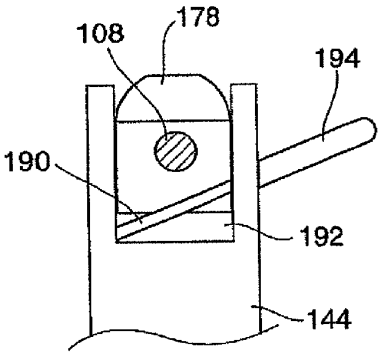

FIG. 35

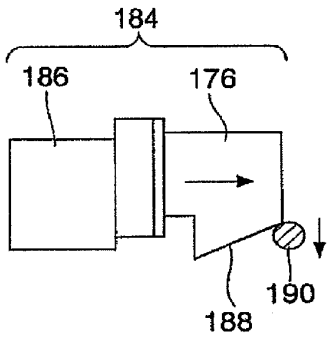

FIG. 36A

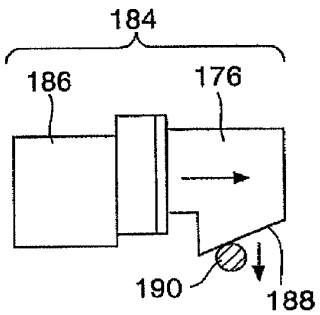

FIG. 36B

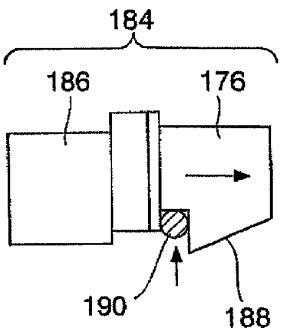

FIG. 36C

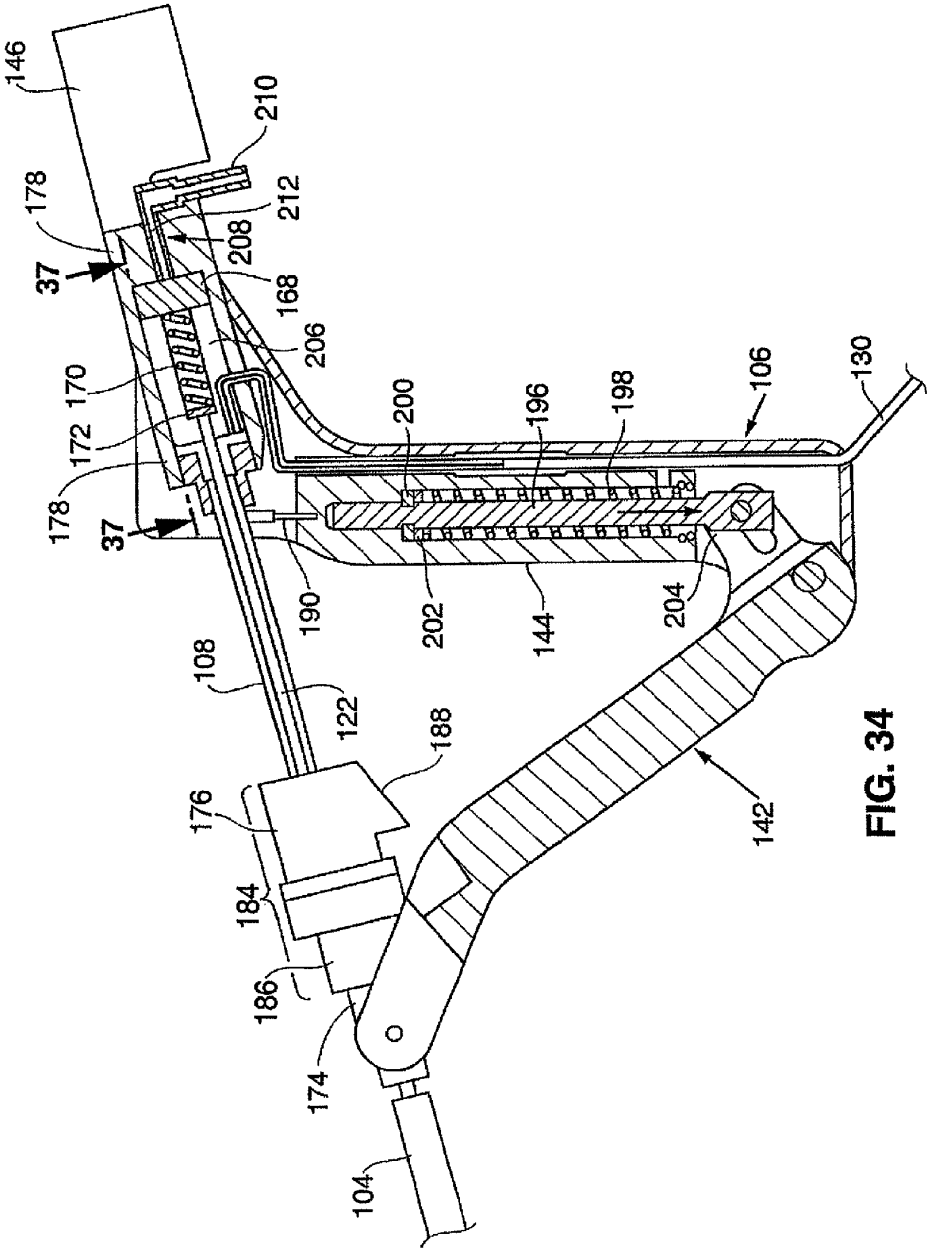

FIG. 34

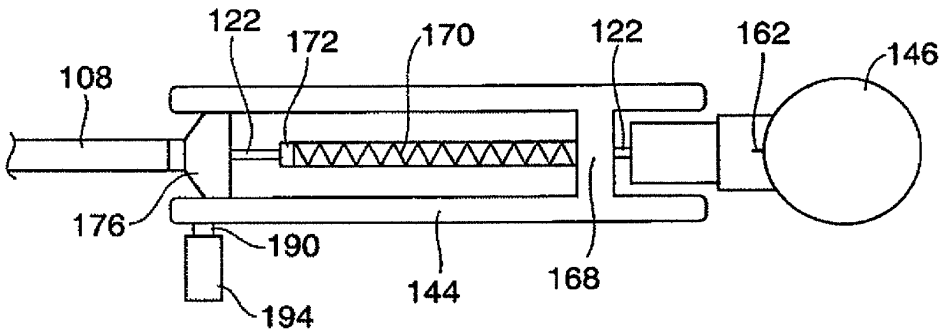

FIG. 37A

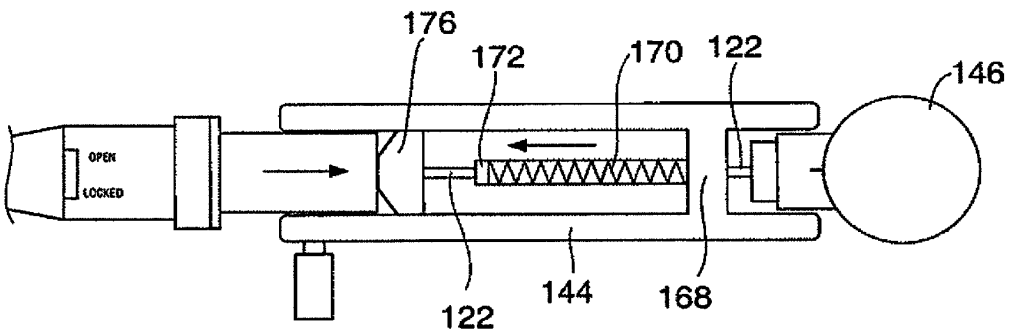

FIG. 37B

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/581,506 filed Oct. 19, 2009, now U.S. Pat. No. 8,506,563 which is a continuation of U.S. application Ser. No. 10/959,771 filed Oct. 6, 2004, now U.S. Pat. No. 7,604,633, which is a divisional of U.S. application Ser. No. 09/103,072 filed Jun. 23, 1998, now U.S. Pat. No. 6,813,520, which claims the benefit of U.S. provisional application 60/084,791 filed May 8, 1998.

FIELD OF THE INVENTION

The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.

BACKGROUND OF THE INVENTION

Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

U.S. Pat. No. 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Pat. No. 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

These ablation devices are satisfactory for carrying out ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only be done by assumption.

For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation. Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C., the fluid within the tissue begins to boil and to thereby produce steam. Because ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

SUMMARY OF THE INVENTION

The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

FIG. **2** is a front elevation view of the ablation device of FIG. **1**, with the handle shown in cross-section and with the RF applicator head in an open condition.

FIG. **3** is a side elevation view of the ablation device of FIG. **2**.

FIG. **4** is a top plan view of the ablation device of FIG. **2**.

FIG. **5**A is a front elevation view of the applicator head and a portion of the main body of the ablation device of FIG. **2**, with the main body shown in cross-section.

FIG. **5**B is a cross-section view of the main body taken along the plane designated **5**B-**5**B in FIG. **5**A.

FIG. **6** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

FIG. **7** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

FIG. **8** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the RF applicator head in the closed condition.

FIG. **9** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

FIG. **10** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

FIG. **11** is a cross-section view of a distal portion of an RF ablation device similar to FIG. **1** which utilizes an alternative spring member configuration for the RF applicator head.

FIG. **12** is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of FIG. **1**, which utilizes an RF applicator head having a modified shape.

FIG. **13** is a top plan view of the ablation device of FIG. **12**.

FIG. **14** is a representation of a bleeding vessel illustrating use of the ablation device of FIG. **12** for general bleeding control.

FIGS. **15** and **16** are representations of a uterus illustrating use of the ablation device of FIG. **12** for endometrial ablation.

FIG. **17** is a representation of a prostate gland illustrating use of the ablation device of FIG. **12** for prostate ablation.

FIG. **18** is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

FIGS. **19**A-**19**C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

FIG. **20** is a side elevation view, similar to the view of FIG. **2**, showing an ablation device according to the present invention in which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

FIG. **21** is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

FIG. **22** is a side elevation view of the ablation device of FIG. **21**, showing the array in the deployed state.

FIG. **23** is a top plan view of the applicator head of the apparatus of FIG. **21**.

FIG. **24** is a cross-sectional top view of the encircled region designated **24** in FIG. **23**.

FIG. **25**A is a perspective view of the electrode array of FIG. **23**.

FIG. **25**B is a distal end view of the applicator head of FIG. **30**A.

FIG. **26**A is a plan view of a knit that may be used to form the applicator head.

FIG. **26**B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of FIG. **26**A.

FIGS. **27**A, **27**B, **27**C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

FIG. **28** is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of FIG. **23**.

FIG. **29** is a cross-section view of a flexure taken along the plane designated **29**-**29** in FIG. **23**.

FIG. **30** is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

FIG. **31** is a cross-sectional side view of the bobbin portion of the apparatus of FIG. **21**.

FIG. **32**A is a side elevation view of the handle of the ablation device of FIG. **21**.

FIG. **32**B is a top plan view of the handle of the ablation device of FIG. **21**. For clarity, portions of the proximal and distal grips are not shown.

FIG. **33** illustrates placement of the applicator head according to the present invention in a uterine cavity.

FIG. **34** is a side elevation view of the handle of the ablation apparatus of FIG. **21**, showing portions of the apparatus in cross-section.

FIG. **35** is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated **35**-**35** in FIG. **32**B.

FIGS. **36**A, **36**B, and **36**C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

FIGS. **37**A and **37**B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated **37**-**37** in FIG. **34** and illustrating one of the load limiting features of the second embodiment. FIG. **37**A shows the condition of the compression spring before the heel member moves into abutment with frame member, and FIG. **37**B shows the condition of the spring after the heel member moves into abutment with the frame member.

DETAILED DESCRIPTION

The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION"; and U.S. Provisional Patent Application No. 60/084,712 filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE".

The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment—Structure

Referring to FIGS. **1** and **2**, an ablation device according to the present invention is comprised generally of three major components: RF applicator head **2**, main body **4**, and handle **6**. Main body **4** includes a shaft **10**. The RF applicator head **2** includes an electrode carrying means **12** mounted to the distal end of the shaft **10** and an array of electrodes **14** formed on the surface of the electrode carrying means **12**. An RF generator **16** is electrically connected to the electrodes **14** to provide mono-polar or bipolar RF energy to them.

Shaft **10** is an elongate member having a hollow interior. Shaft **10** is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar **13** is formed on the exterior of the shaft **10** at the proximal end.

As best shown in FIGS. **6** and **7**, passive spring member **15** are attached to the distal end of the shaft **10**.

Extending through the shaft **10** is a suction/insufflation tube **17** (FIGS. **6-9**) having a plurality of holes **17***a* formed in its distal end. An arched active spring member **19** is connected between the distal ends of the passive spring members **15** and the distal end of the suction/insufflation tube **17**.

Referring to FIG. **2**, electrode leads **18***a* and **18***b* extend through the shaft **10** from distal end **20** to proximal end **22** of the shaft **10**. At the distal end **20** of the shaft **10**, each of the leads **18***a*, **18***b* is coupled to a respective one of the electrodes **14**. At the proximal end **22** of the shaft **10**, the leads **18***a*, **18***b* are electrically connected to RF generator **16** via an electrical connector **21**. During use, the leads **18***a*, **18***b* carry RF energy from the RF generator **16** to the electrodes. Each of the leads **18***a*, **18***b* is insulated and carries energy of an opposite polarity than the other lead.

Electrically insulated sensor leads **23***a*, **23***b* (FIGS. **5**A and **5**B) also extend through the shaft **10**. Contact sensors **25***a*, **25***b* are attached to the distal ends of the sensor leads **23***a*, **23***b*, respectively and are mounted to the electrode carrying means **12**. During use, the sensor leads **23***a*, **23***b* are coupled by the connector **21** to a monitoring module in the RF generator **16** which measures impedance between the sensors **25***a*, **25***b*. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

Referring to FIG. **5**B, electrode leads **18***a*, **18***b* and sensor leads **23***a*, **23***b* extend through the shaft **10** between the external walls of the tube **17** and the interior walls of the shaft **10** and they are coupled to electrical connector **21** which is preferably mounted to the collar **13** on the shaft **10**. Connector **21**, which is connectable to the RF generator **16**, includes at least four electrical contact rings **21***a*-**21***d* (FIGS. **1** and **2**) which correspond to each of the leads **18***a*, **18***b*, **23***a*, **23***b*. Rings **21***a*, **21***b* receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings **21***c*, **21***d* deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator **16**.

Referring to FIG. **5**A, the electrode carrying means **12** is attached to the distal end **20** of the shaft **10**. A plurality of holes **24** may be formed in the portion of the distal end **20** of the shaft which lies within the electrode carrying means **12**.

The electrode carrying means **12** preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in FIGS. **1** through **11** has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means **12** shown in these figures includes horn regions **26** which during use are positioned within the cornual regions of the uterus and which therefore extend towards the fallopian tubes.

Electrode carrying means **12** is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

Electrodes **14** are preferably attached to the outer surface of the electrode carrying means **12**, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means **12** by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means **12** is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

For example, by using 3-6 mm spacing and an electrode width of approximately 0.5-2.5 mm, delivery of approximately 20-40 watts over a 9-16 cm2 target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2-3 mm when the active electrode surfaces covers less than 1% of the target tissue area. This can be better understood with reference to FIG. **19**A, in which high surface density electrodes are designated **14***a* and low surface density electrodes are designated **14***b*. For purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in FIG. **19**A.

As is apparent from FIG. **19**A, the electrodes **14***a*, which have more active area in contact with the underlying tissue T, produce a region of ablation A**1** that extends more deeply into the tissue T than the ablation region A**2** produced by the low density electrodes **14***b*, even though the electrode spacings and widths are the same for the high and low density electrodes.

Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	1-3 mm
1-2.5 mm	3-6 mm	5-7 mm
1-4.5 mm	8-10 mm	8-10 mm

Examples of electrode widths, having spacings with less than 1% active electrode surface coverage, and their resultant

ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	0.5-1 mm
1-2.S mm	3-6 mm	2-3 mm
1-4.5 mm	8-10 mm	2-3 mm

Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

In the preferred embodiment, the preferred electrode spacing is approximately 8-10 mm in the horn regions **26** with the active electrode surfaces covering approximately 1% of the target region. Approximately 1-2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated **28**) and approximately 3-6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

The RF generator **16** may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to FIG. **18**.

Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes may be arranged in any pattern to provide ablation to desired depths.

Referring to FIGS. **6** and **7**, an introducer sheath **32** facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath **32** is a tubular member which is telescopically slidable over the shaft **10**. The sheath **32** is slidable between a distal condition, shown in FIG. **6**, in which the electrode carrying means **12** is compressed inside the sheath, and a proximal condition in which the sheath **32** is moved proximally to release the electrode carrying means from inside it (FIG. **7**). By compressing the electrode carrying means **12** to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

A handle **34** attached to the sheath **32** provides finger holds to allow for manipulation of the sheath **32**. Handle **34** is slidably mounted on a handle rail **35** which includes a sleeve **33**, a finger cutout **37**, and a pair of spaced rails **35***a*, **35***b* extending between the sleeve **33** and the finger cutout **37**. The shaft **10** and sheath **32** slidably extend through the sleeve **33** and between the rails **35***a*, **35***b*. The tube **17** also extends through the sleeve **33** and between the rails **35***a*, **35***b*, and its proximal end is fixed to the handle rail **35** near the finger cutout **37**.

A compression spring **39** is disposed around the proximal most portion of the suction/insufflation tube **17** which lies between the rails **35***a*, **35***b*. One end of the compression spring **39** rests against the collar **13** on the shaft **10**, while the opposite end of the compression spring rests against the handle rail **35**. During use, the sheath **32** is retracted from the electrode carrying means **12** by squeezing the handle **34** towards the finger cutout **37** to slide the sheath **32** in the distal direction. When the handle **34** advances against the collar **13**, the shaft **10** (which is attached to the collar **13**) is forced to slide in the proximal direction, causing compression of the spring **39** against the handle rail **35**. The movement of the shaft **10** relative to the suction/insufflation tube **17** causes the shaft **10** to pull proximally on the passive spring member **15**. Proximal movement of the passive spring member **15** in turn pulls against the active spring member **19**, causing it to move to the opened condition shown in FIG. **7**. Unless the shaft is held in this retracted condition, the compression spring **39** will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

The amount by which the springs **15**, **19** are spread may be controlled by manipulating the handle **34** to slide the shaft **10** (via collar **13**), proximally or distally. Such sliding movement of the shaft **10** causes forceps-like movement of the spring members **15**, **19**.

A flow pathway **36** is formed in the handle rail **35** and is fluidly coupled to a suction/insufflation port **38**. The proximal end of the suction/insufflation tube **17** is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube **17** via the suction/insufflation port **38**. For example, suction may be applied to the fluid port **38** using a suction/insufflation unit **40**. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means **12**, into the suction/insufflation tube **17** via holes **17***a*, through the tube **17**, and through the suction/insufflation unit **40** via the port **38**. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube **17** via the port **38**. The insufflation gas travels through the tube **17**, through the holes **17***a*, and into the uterine cavity through the permeable electrode carrying member **12**.

If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen **42**, **44**, and **46** may be formed in the walls of the introducer sheath **32** as shown in FIG. **5**B. An imaging conduit, such as a fiberoptic cable **48**, extends through lumen **42** and is coupled via a camera cable **43** to a camera **45**. Images taken from the camera may be displayed on a monitor **56**. An illumination fiber **50** extends through lumen **44** and is coupled to an illumination source **54**. The third lumen **46** is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

Because during use it is most desirable for the electrodes **14** on the surface of the electrode carrying means **12** to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means **12** may be provided to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

For example, referring to FIG. **11**, alternative spring members **15***a*, **19***a* may be attached to the shaft **10** and biased such that, when in a resting state, the spring members are positioned in the fully resting condition shown in FIG. **11**. Such spring members would spring to the resting condition upon withdrawal of the sheath **32** from the RF applicator head **2**.

Alternatively, a pair of inflatable balloons **52** may be arranged inside the electrode carrying means **12** as shown in FIG. **20** and connected to a tube (not shown) extending through the shaft **10** and into the balloons **52**. After insertion of the apparatus into the organ and following retraction of the sheath **32**, the balloons **52** would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port **38** using an apparatus similar to the suction/insufflation apparatus **40**.

Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end **22***a* of the suction/insufflation tube **17**. Application of suction using the suction/insufflation device **40** would draw the organ tissue towards the electrode carrying means **12** and thus into better contact with the electrodes **14**.

FIGS. **12** and **13** show an alternative embodiment of an ablation device according to the present invention. In the alternative embodiment, an electrode carrying means **12***a* is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (FIG. **14**), tissue ablation in the prostate gland (FIG. **17**), and also intrauterine ablation (FIGS. **15** and **16**).

First Exemplary Embodiment—Operation

Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

Referring to FIG. **1**, the device is initially configured for use by positioning the introducer sheath **32** distally along the shaft **10**, such that it compresses the electrode carrying means **12** within its walls.

At this time, the electrical connector **21** is connected to the RF generator **16**, and the fiberoptic cable **48** and the illumination cable **50** are connected to the illumination source, monitor, and camera, **54**, **56**, **45**. The suction/insufflation unit **40** is attached to suction/insufflation port **38** on the handle rail **35**. The suction/insufflation unit **40** is preferably set to deliver carbon dioxide at an insufflation pressure of 20-200 mmHg.

Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in FIG. **6**, until the distal end of the introducer sheath **32** contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube **17** via the port **38**, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera **45** and monitor **56**) the internal cavities using images detected by a fiberoptic cable **48** inserted through lumen **42**. If, upon observation, the physician determines that a tissue biopsy or other procedure is needed, the required instruments may be inserted into the uterine cavity via the instrument channel **46**.

Following insertion, the handle **34** is withdrawn until it abuts the collar **13**. At this point, the sheath **32** exposes the electrode carrying member **12** but the electrode carrying member **12** is not yet fully expanded (see FIG. **9**), because the spring members **15**, **19** have not yet been moved to their open condition. The handle **34** is withdrawn further, causing the shaft **10** to move proximally relative to the suction/insufflation tube **17**, causing the passive spring members **15** to pull the active spring members **19**, causing them to open into the opened condition shown in FIG. **10**.

The physician may confirm proper positioning of the electrode carrying member **12** using the monitor **56**, which displays images from the fiberoptic cable **48**.

Proper positioning of the device and sufficient contact between the electrode carrying member **12** and the endometrium may further be confirmed using the contact sensors **25***a*, **25***b*. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20-180 ohm, depending on the water content of the endometrial lining.

The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member **12**, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors **25***a*, **25***b* that there is sound contact between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

Next, insufflation is terminated. Approximately 1-5 cc of saline may be introduced via suction/insufflation tube **17** to initially wet the electrodes and to improve electrode electrical contact with the tissue. After introduction of saline, the suction/insufflation device **40** is switched to a suctioning mode. As described above, the application of suction to the RF applicator head **2** via the suction/insufflation tube **17** collapses the uterine cavity onto the RF applicator head **2** and thus assures better contact between the electrodes and the endometrial tissue.

If the generally tubular apparatus of FIGS. **12** and **13** is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. FIGS. **15** and **16**.

Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in FIG. **5***a*, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F**1**, F**2** and F**4** in FIG. **18**, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in FIG. **18**, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F**2** which results from energization of electrodes having a non-energized electrode between them, or pattern F**4** which results from energization of electrodes having three non-energized electrodes between them).

Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see FIG. **19**A). Referring to FIG. **19**B, if multiple, closely spaced, electrodes **14** are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in FIG. **19**B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

As another example, shown in FIG. **19**C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member **12** and is thereby drawn away from the electrodes. The moisture may pass through the holes **17***a* in the suction/insufflation tube **17** and leave the suction/insufflation tube **17** at its proximal end via port **38** as shown in FIG. **7**. Moisture removal from the ablation site may be further facilitated by the application of suction to the shaft **10** using the suction/insufflation unit **40**.

Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

Once the process has self terminated, 1-5 cc of saline can be introduced via suction/insufflation tube **17** and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction insufflation device **40** is then switched to provide insufflation of carbon dioxide at a pressure of 20-200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head **2** and to thus ease the closing of the RF applicator head. The RF applicator head **2** is moved to the closed position by sliding the handle **34** in a distal direction to fold the spring members **15**, **19** along the axis of the device and to cause the introducer sheath **32** to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor **56**. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment—Structure

A second embodiment of an ablation device **100** in accordance with the present invention is shown in FIGS. **21**-**37**B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

Referring to FIGS. **21** and **22**, the second embodiment includes an RF applicator head **102**, a sheath **104**, and a handle **106**. As with the first embodiment, the applicator head **102** is slidably disposed within the sheath **104** (FIG. **21**) during insertion of the device into the uterine cavity, and the handle **106** is subsequently manipulated to cause the applicator head **102** to extend from the distal end of the sheath **104** (FIG. **22**) and to expand into contact with body tissue (FIG. **33**).

RF Applicator Head

Referring to FIG. **23**, in which the sheath **104** is not shown for clarity, applicator head **102** extends from the distal end of a length of tubing **108** which is slidably disposed within the sheath **104**. Applicator head **102** includes an external electrode array **102***a* and an internal deflecting mechanism **102***b* used to expand and tension the array for positioning into contact with the tissue.

Referring to FIGS. **25**A and **25**B, the array **102***a* of applicator head **102** is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in FIGS. **26**A and **26**B) is formed of three monofilaments of nylon **109***a* knitted together with single yarns of spandex **109***b*. Each yarn of spandex **109***b* has a double helix **109***c* of five nylon monofilaments coiled around it.

This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially elongates from its coiled configuration.

One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere. Next, the insulating regions **110** (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface, is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

The mesh may be configured in a variety of shapes, including but not limited to the triangular shape S**1**, parabolic S**2**, and rectangular S**3** shapes shown in FIGS. **27**A, **27**B and **27**C, respectively.

Turning again to FIGS. **25**A and **25**B, when in its expanded state, the array **102***a* includes a pair of broad faces **112** spaced apart from one another. Narrower side faces **114** extend between the broad faces **112** along the sides of the applicator head **102**, and a distal face **116** extends between the broad faces **112** at the distal end of the applicator head **102**.

Insulating regions **110** are formed on the applicator head to divide the mesh into electrode regions. The insulated regions **110** are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

The array may be divided by the insulated regions **110** into a variety of electrode configurations. In a preferred configuration the insulating regions **110** divide the applicator head

into four electrodes **118***a*-**118***d* by creating two electrodes on each of the broad faces **112**. To create this four-electrode pattern, insulating regions **110** are placed longitudinally along each of the broad faces **112** as well as along the length of each of the faces **114**, **116**. The electrodes **118***a*-**118***d* are used for ablation and, if desired, to measure tissue impedance during use.

Deflecting mechanism **102***b* and its deployment structure is enclosed within electrode array **102***a*. Referring to FIG. **23**, external hypotube **120** extends from tubing **108** and an internal hypotube **122** is slidably and co-axially disposed within hypotube **120**. Flexures **124** extend from the tubing **108** on opposite sides of external hypotube **120**. A plurality of longitudinally spaced apertures **126** (FIG. **28**) are formed in each flexure **124**. During use, apertures **126** allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube **120** using a vacuum source fluidly coupled to hypotube **120**.

Each flexure **124** preferably includes conductive regions that are electrically coupled to the array **102***a* for delivery of RF energy to the body tissue. Referring to FIG. **29**, strips **128** of copper tape or other conductive material extend along opposite surfaces of each flexure **124**. Each strip **128** is electrically insulated from the other strip **128** by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips **128** and extend through tubing **108** (FIG. **23**) to an electrical cord **130** (FIG. **21**) which is attachable to the RF generator.

During use, one strip **128** on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures **124** may instead be used for electrically connecting the electrode array to the source of RF energy.

It is important to ensure proper alignment between the conductive regions of the flexures **124** (e.g. copper strips **128**) and the electrodes **118***a*-**118***d* in order to maintain electrical contact between the two. Strands of thread **134** (which may be nylon) (FIG. **23**) are preferably sewn through the array **102***a* and around the flexures **124** in order to prevent the conductive regions **128** from slipping out of alignment with the electrodes **118***a*-**118***d*. Alternate methods for maintaining contact between the array **102***a* and the conductive regions **128** include using tiny bendable barbs extending between the flexures **124** and the array **102***a* to hook the array to the conductive regions **128**, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

Referring again to FIG. **23**, internal flexures **136** extend laterally and longitudinally from the exterior surface of hypotube **122**. Each internal flexure **136** is connected at its distal end to one of the flexures **124** and a transverse ribbon **138** extends between the distal portions of the internal flexures **136**. Transverse ribbon **138** is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in FIG. **23** and such that when in a compressed condition it is folded along the plurality of creases **140** that extend along its length. Flexures **124**, **136** and ribbon **138** are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

The deflecting mechanism is preferably configured such that the distal tips of the flexures **124** are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections **124***a* (FIG. **28**) of the flexures from a material that is more flexible than the proximal sections **124***b*. For example, flexures **124** may be provided to have proximal sections formed of a material having a modulus of approximately 28×106 psi and distal sections having a durometer of approximately 72D.

Alternatively, referring to FIG. **30**, the flexures **124** may be joined to the internal flexures **136** at a location more proximal than the distal tips of the flexures **124**, allowing them to move more freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in FIG. **30**). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

The deflecting mechanism formed by the flexures **124**, **136**, and ribbon **138** forms the array into the substantially triangular shape shown in FIG. **23**, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips **142**, **144** forming handle **106** are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube **120** and relative forward motion of the hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deploys and tensions the electrode array **102***a*.

Measurement Device

The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge **146** (FIG. **21**). The measurement device utilizes non-conductive (e.g. nylon) suturing threads **148** that extend from the hypotube **122** and that have distal ends attached to the distal portion of the deflecting mechanism (FIG. **23**). As shown in FIG. **24**, threads **148** are preferably formed of a single strand **150** threaded through a wire loop **152** and folded over on itself. Wire loop **152** forms the distal end of an elongate wire **154** which may be formed of stainless steel or other wire.

Referring to FIG. **31**, wire **154** extends through the hypotube **122** and is secured to a rotatable bobbin **156**. The rotatable bobbin **156** includes a dial face **158** preferably covered in a clear plastic. As can be seen in FIG. **32***b*, dial face **158** includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing **160** and a corresponding marker line **162** is printed on the gauge housing. A torsion spring **164** provides rotational resistance to the bobbin **156**.

Expansion of the applicator head **102** during use pulls threads **148** (FIG. **23**) and thus wire **154** (FIG. **24**) in a distal direction. Wire **154** pulls against the bobbin **156** (FIG. **31**), causing it to rotate. Rotation of the bobbin positions one of the calibration markings on dial face **158** into alignment with the marker line **162** (FIG. **32**B) to indicate the distance between the distal tips of flexures **124** and thus the uterine width.

The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures **124** and to electronically transmit the uterine width to the RF generator.

Control of Ablation Depth

The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2-3 mm for the cervical os and the cornual regions, and approximately 7-8 mm in the main body of the uterus where the endometrium is substantially thicker.

As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can been seen with reference to FIG. **33** that the center to center distance d**1** between the electrodes **118***a*, **118***b* is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d**2** between electrodes **118***a*, **118***b* is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d**3** extend between top and bottom electrodes **118***b*, **118***c* and **118***a*, **118***d* and again contribute to shallower ablation.

Naturally, because the array **102***a* expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array **102***a* vary. One embodiment of the array **102***a* includes a range of widths of at least approximately 2.5-4.5 cm, a range of lengths of at least approximately 4-6 cm, and a density of approximately 35%-45%.

The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head **102** and displayed on gauge **146**. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following relationship:

$$P=L\times W\times 5.5$$

Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

Handle

Referring again to FIGS. **21** and **22**, the handle **106** of the RF ablation device according to the second embodiment includes a distal grip section **142** and a proximal grip section **144** that are pivotally attached to one another at pivot pin **166**.

The proximal grip section **144** is coupled to the hypotube **122** (FIG. **23**) via yoke **168**, overload spring **170** and spring stop **172**, each of which is shown in the section view of FIG. **34**. The distal grip section **142** is coupled to the external hypotube **120** via male and female couplers **174**, **176** (see FIGS. **32**A and **32**B). Squeezing the grip sections **142**, **144** towards one another thus causes relative movement between the external hypotube **120** and the internal hypotube **122**. This relative sliding movement results in deployment of the deflecting mechanism **102***b* from the distal end of the sheath and expansion of the array **102***a* to its expanded state.

Referring to FIGS. **32**A and B, rack **180** is formed on male coupler **174** and calibration markings **182** are printed adjacent the rack **180**. The calibration markings **182** correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

A sliding collar **184** is slidably disposed on the tubing **108** and is slidable over male coupler **174**. Sliding collar **184** includes a rotating collar **186** and a female coupler **176** that includes a wedge-shaped heel **188**. A locking spring member **190** (FIGS. **32**B and **35**) extends across an aperture **192** formed in the proximal grip **144** in alignment with the heel **188**. When the distal and proximal handle sections are squeezed together to deploy the array, the heel **188** passes into the aperture **192**. Its inclined lower surface gradually depresses the spring member **190** as the heel moves further into the aperture **192**. See FIGS. **36**A and **36**B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See FIG. **36**C.

A release lever **194** (FIG. **35**) is attached to the free end of the spring member **190**. To disengage the spring lock, release lever **194** is depressed to lower spring member **190** so that the inclined heel can pass over the spring member and thus out of the aperture **192**.

Referring again to FIGS. **32**A and **32**B, sliding collar **184** is configured to allow the user to limit longitudinal extension of the array **102***a* to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler **174** relative to the female coupler **176** using the rotating collar **186** to lock and unlock the female coupler from the rack **180** and the male coupler **174**. Locking the female coupler to the rack **180** and male coupler **174** will limit extension of the array to approximately the predetermined uterine length, as shown on the calibration markings **182**.

Once the uterine length has been measured using a conventional sound, the user positions sliding collar **184** adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section **186** to engage its internally positioned teeth with the

rack **180**. This locks the longitudinal position of the heel **188** such that it will engage with the spring member **190** on the proximal grip when the array has been exposed to the length set by the sliding collar.

The handle **106** includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array **102***a*. One of the spring assemblies controls movement of the grips **142**, **144** to automatically stow the array **102***a* into the sheath **104** when the user stops squeezing the grips **142**, **144** towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures **124** to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism **102***b*.

FIG. **34** shows the distal and proximal grips **142** and **144** in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel **196** that is slidably disposed within the proximal grip **144**. A compression spring **198** surrounds a portion of the return mandrel **196**, and a retaining ring **200** is attached to the mandrel **196** above the spring **198**. A spring stop **202** is disposed between the spring **198** and the retaining ring.

The lowermost end of the return mandrel **196** is pivotally engaged by a coupling member **204** on distal grip **142**. Relative movement of the grips **142**, **144** towards one another causes the coupling member **204** to pull the return member downwardly with the proximal grip **144** as indicated by arrows. Downward movement of the mandrel **196** causes its retaining ring **200** and spring stop **202** to bear downwardly against the compression spring **198**, thereby providing a movement which acts to rotate the grips **142**, **144** away from one another. When tension against the grips **142**, **144** is released (assuming that heel **188** is not locked into engagement with spring member **190**) the grips rotate apart into the opened position as the compression spring **198** returns to the initial state, stowing the applicator head inside the sheath.

The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member **178** disposed over yoke **168**, which is pivotally attached to proximal grip **144**. Tubing **108** extends from the array **102***a* (see FIG. **23**), through the sheath **104** and is fixed at its proximal end to the frame member **178**. Hypotube **122** does not terminate at this point but instead extends beyond the proximal end of tubing **108** and through a window **206** in the frame member. Its proximal end **208** is slidably located within frame member **178** proximally of the window **206** and is fluidly coupled to a vacuum port **210** by fluid channel **212**. Hypotube **120** terminates within the frame. Its proximal end is fixed within the distal end of the frame.

A spring stop **172** is fixed to a section of the hypotube within the window **206**, and a compression spring **170** is disposed around the hypotube between the spring stop **172** and yoke **168**. See FIGS. **32**B and **34**.

When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath **104** from the array **102***a*. Referring to FIGS. **37**A and **37**B, this motion continues until female coupler **176** contacts and bears against frame member **178**. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube **120**. An opposing force is developed in yoke **168**, which causes a relative forward motion in hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deflect in a manner that deploys and tensions the electrode array. Compression spring **170** acts to limit the force developed by the operator against hypotubes **120**, **122**, thus limiting the force of flexures **124**, **136** acting on the array and the target tissue surrounding the array.

Referring to FIG. **21**, collar **214** is slidably mounted on sheath **104**. Before the device is inserted into the uterus, collar **214** can be positioned along sheath **104** to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head **102** has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar **214** can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

Second Exemplary Embodiment—Operation

In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar **184** (FIG. **32**B) adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section **186** to engage its internally positioned teeth with the rack **180**. This locks the longitudinal position of the heel **188** (FIG. **32**A) such that it will engage with the spring member **190** when the array has been exposed to the length set by the sliding collar.

Next, with the grips **142**, **144** in their resting positions to keep the applicator head **102** covered by sheath **104**, the distal end of the device **100** is inserted into the uterus. Once the distal end of the sheath **104** is within the uterus, grips **142**, **144** are squeezed together to deploy the applicator head **102** from sheath **104**. Grips **142**, **144** are squeezed until heel **188** engages with locking spring member **190** as described with respect to FIGS. **36**A through **36**C.

At this point, deflecting mechanism **102***b* has deployed the array **102***a* into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge **146**. The measured length and width are entered into the RF generator system **250** (FIG. **21**) and used to calculate the ablation power.

Vacuum source **252** (FIG. **21**) is activated, causing application of suction to hypotube **122** via suction port **210**. Suction helps to draw uterine tissue into contact with the array **102**.

Ablation power is supplied to the electrode array **102***a* by the RF generator system **250**. The tissue is heated as the RF energy passes from electrodes **118***a-d* to the tissue, causing moisture to be released from the tissue. The vacuum source **252** helps to draw moisture from the uterine cavity into the hypotube **122**. Moisture withdrawal is facilitated by the apertures **126** formed in flexures **124** by preventing moisture from being trapped between the flexures **124** and the lateral walls of the uterus.

If the RF generator **250** includes an impedance monitoring module, impedance may be monitored at the electrodes **118***a-d* and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever **194** to disengage heel **188** from locking spring member **190** and to thereby allow grips **142**, **144** to move to their expanded (resting) condition. Release of grips **142**, **144** causes applicator head **102** to retract to its unexpanded condition and further causes applicator head **102** to be withdrawn into the sheath **104**. Finally, the distal end of the device **100** is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

We claim:

1. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

2. The device of claim **1** further comprising a transverse ribbon coupled to a distal end of the first and second external flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state.

3. The device of claim **1** wherein the first internal flexure includes a plurality of longitudinally spaced apertures.

4. The device of claim **1** wherein the proximal grip is coupled to the inner sleeve and the distal grip is coupled to the outer sleeve.

5. The device of claim **1** further comprising an introducer sheath, wherein the inner sleeve and the outer sleeve are disposed within the introducer sheath when the applicator head is in the contracted state, and wherein the distal grip is coupled to the introducer sheath so that proximal movement of the distal grip causes the introducer sheath to move proximally relative to the applicator head.

6. The device of claim **5**, wherein continued movement of the proximal grip and distal grip closer together causes relative movement between the inner sleeve and the outer sleeve.

7. The device of claim **1** wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

8. The device of claim **1** further comprising an adjustable locking mechanism configured to limit a degree of expansion of the applicator head.

9. The device of claim **1** further comprising an adjustable locking mechanism configured to limit a distance by which a user can move the proximal grip and the distal grip closer together.

10. The device of claim **1** wherein the first and second external flexures each have a distal end, and wherein the first and second internal flexures are coupled to the first and second external flexures at a location proximal to the distal ends of the first and second external flexures.

11. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve:

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

12. The device of claim **1** wherein the applicator head is configured to expand until limited by the dimension of the uterus.

13. The device of claim **11** wherein the first internal flexure includes a plurality of longitudinally spaced apertures.

14. The device of claim **11** further comprising an adjustable locking mechanism configured to limit a degree of expansion of the applicator head.

15. The device of claim **11** wherein the first and second external flexures each have a distal end, and wherein the first and second internal flexures are coupled to the first and second external flexures at a location proximal to the distal ends of the first and second external flexures.

* * * * *

LIMBACH & LIMBACH L.L.P.
2001 F rry Building, San Francisco, CA 94111
415/433-4150

Address to:
Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Attorney's Docket No. ENVS-220
First Named Inventor Csaba Truckai

UTILITY PATENT APPLICATION TRANSMITTAL
(under 37 CFR 1.53(b))

THIS APPLICATION CLAIMS THE BENEFIT OF U.S. PROVISIONAL APPLICATION NO. 60/084,791, FILED MAY 8, 1998, AND IS A CONTINUATION-IN-PART OF COPENDING U.S. APPLICATION NO. 08/632,516, FILED APRIL 12, 1996, NOW U.S. PATENT NO. 5,769,880, ISSUED JUNE 23, 1998.

Transmitted herewith for filing is a **CONTINUATION-IN-PART** patent application entitled:

A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

CERTIFICATION UNDER 37 CFR § 1.10

I hereby certify that this New Application and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date June 23, 1998, in an envelope bearing "Express Mail Post Office To Addressee" Mailing Label Number EM503277278US addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

ELIZABETH A. REICKER Elizabeth A. Reicker
(Name of person mailing paper) (Signature)

Enclosed are:

1. X Transmittal Form (two copies required)

2. The papers required for filing date under CFR § 1.53(b):
   i. 49 Pages of specification (including claims and abstract);
   ii. 19 Sheets of drawings.
   __ formal X informal

3. Declaration or oath

   a. X Unsigned Declaration (original or copy)

   b. _ Copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Item 12 completed)

   _____ Incorporation By Reference (to be used if Item 3b is checked)

   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Item 3b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

   i. __ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)

4. __ Microfiche Computer Program (Appendix, see 37 CFR 1.96)

5. __ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   i. __ Computer Readable Copy
   ii. __ Paper Copy (identical to computer copy)
   iii. __ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

6. __ An assignment of the invention to is attached (including Form PTO-1595).

__ The prior application is assign d of record to ;
Assignment recorded in PTO on _, Reel _, Frame(s) _.
__ The prior application is assigned, and the assignment (copy attached) was submitted to PTO for recording on _.
i. __ 37 CFR 3.73(b) Statement (when there is an assignee)

7. __ Power of Attorney

8. __ An Information Disclosure Statement (IDS) is enclosed, including a PTO-1449 and copies of __ references.

9. __ Preliminary Amendment.

10. X Return Receipt Postcard (MPEP 503 -- should be specifically itemized)

11. __ Other

12. If a **CONTINUING APPLICATION**, ***check appropriate box and supply the requisite information***

__ Continuation
__ Divisional
X Continuation-In-Part (CIP)

of immediately prior application no. 08/632,516, filed April 12, 1996, now Patent No. 5,769,880, issued June 23, 1998 and claims benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998.

i. RELATE BACK - 35 USC 120: If one of the above boxes are checked, please amend the specification by inserting before the first line the sentence: --This is a continuation-in-part of Application no. 08/632,516, filed April 12, 1996, now Patent No. 5,769,880, issued June 23, 1998 and claims benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998.--

ii. MAINTENANCE OF COPENDENCY OF PRIOR APPLICATION
(This item must be completed and the necessary papers filed in the prior application if the period set in the prior application has run).
[] A petition, fee and response has been filed to extend the term in the pending prior application until _.
[] A copy of the petition for extension of time in the prior application is attached.

iii. CONDITIONAL PETITIONS FOR EXTENSION OF TIME IN PRIOR APPLICATION
(Complete this item and file conditional petition in prior application if previous item (ii) not applicable).
[] A conditional petition for extension of time is being filed in the pending prior application.
[] A copy of the conditional petition for extension of time in the prior application is attached.

13. FOREIGN PRIORITY
[] Priority of application no. _ filed on _ in _ is claimed under 35 USC 119.

The certified copy of the priority application:
_ is filed herewith; or
_ has been filed in prior application no. _ filed on _, or
_ will be provided.

__ English Translation Document (if applicable)

14. **FEE CALCULATION**

a. __ Amendment changing number of claims or deleting multiple dependencies is enclosed.

b. __ Cancel in this application original Claims _ of the prior application before calculating the filing fee.

CLAIMS AS FILED

	Number Filed	Number Extra	Rate	Basic Fee ($790)
Total Claims	31 - 20	* 11	x $22.00	$242.00
Independent Claims	3 - 3	* -0-	x $82.00	-0-
__ Multiple dependent claim(s), if any			$270.00	-0-

*If less than zero, enter "0".

Filing Fee Calculation $1032.00

50% Filing Fee Reduction (if applicable) $516.00

15. Small Entity Status
a. X A small entity statement is enclosed. (unsigned)
b. __ A small entity statement was filed in the prior nonprovisional application and such status is still proper and desired.
c. __ is no longer claimed.

16. Other Fees
__ Recording Assignment [$40.00] . . . . . $
__ Other fees
Specify _____ . . . . . $

Total Fees Enclosed . . . . . $

17. Payment of Fees
__ Check(s) in the amount of $__ enclosed.
__ Charge Account No. 12-1420 in the amount of $__.
A duplicate of this transmittal is attached.

18. All correspondence regarding this application should be forwarded to the undersigned attorney:

Kathleen A. Frost
Limbach & Limbach L.L.P.
2001 Ferry Building
San Francisco, CA 94111
Telephone: 415/433-4150
Facsimile: 415/433-8716

19. Authorization to Charge Additional Fees

X The Commissioner is hereby authorized to charge any additional fees (or credit any overpayment) associated with this communication and which may be required under 37 CFR § 1.16 or § 1.17 to Account No. 12-1420. A duplicate of this transmittal is attached.

LIMBACH & LIMBACH L.L.P.

June 23, 1998
(Date)

By: Kathleen A Frost
Kathleen A. Frost
Registration No. 37,326
Attorney(s) or Agent(s) of Record

Attorney Docket No. ENVS-220
[]

PATENTS\APP-TRAN.MRG
Rev. 01/05/98

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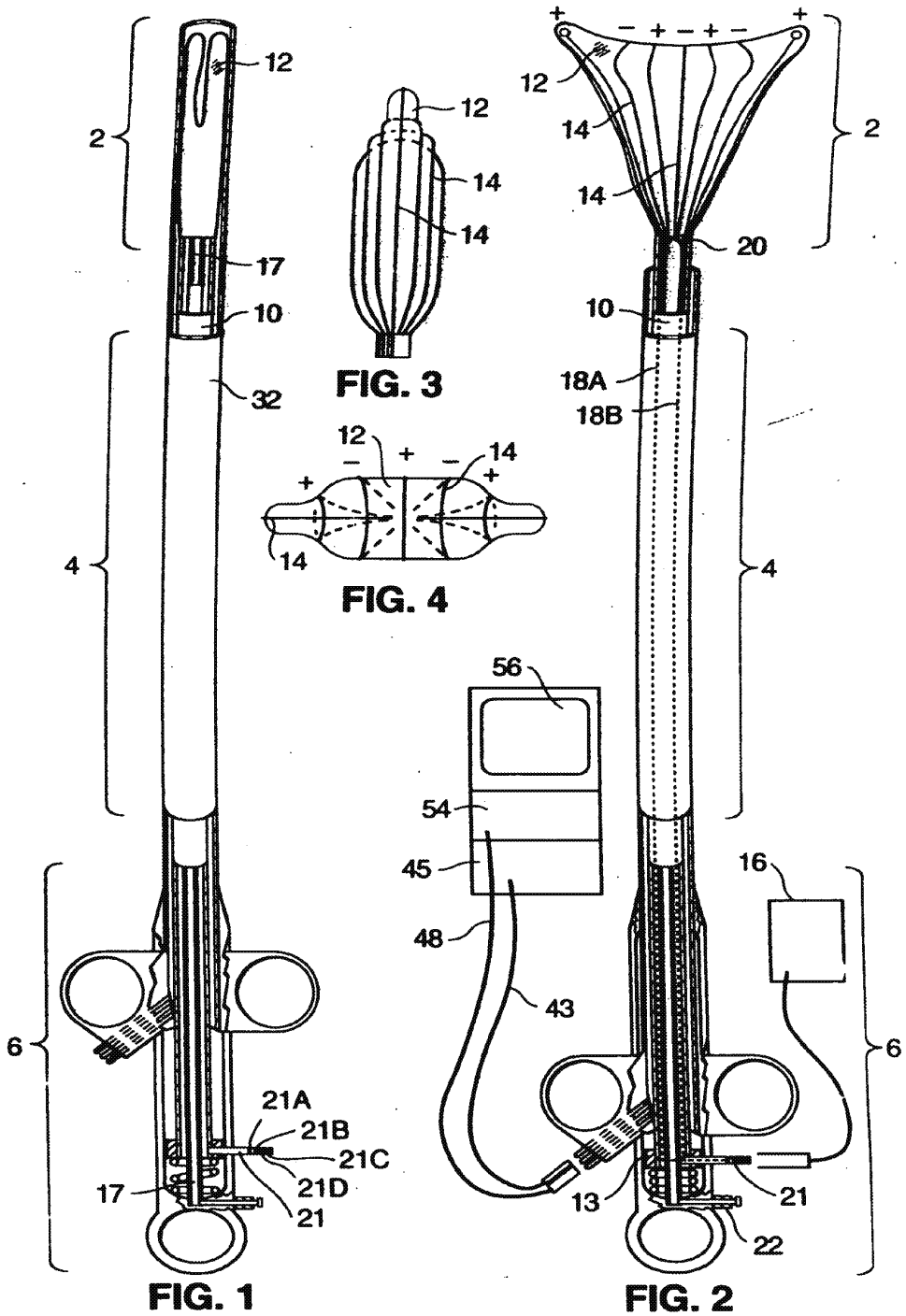

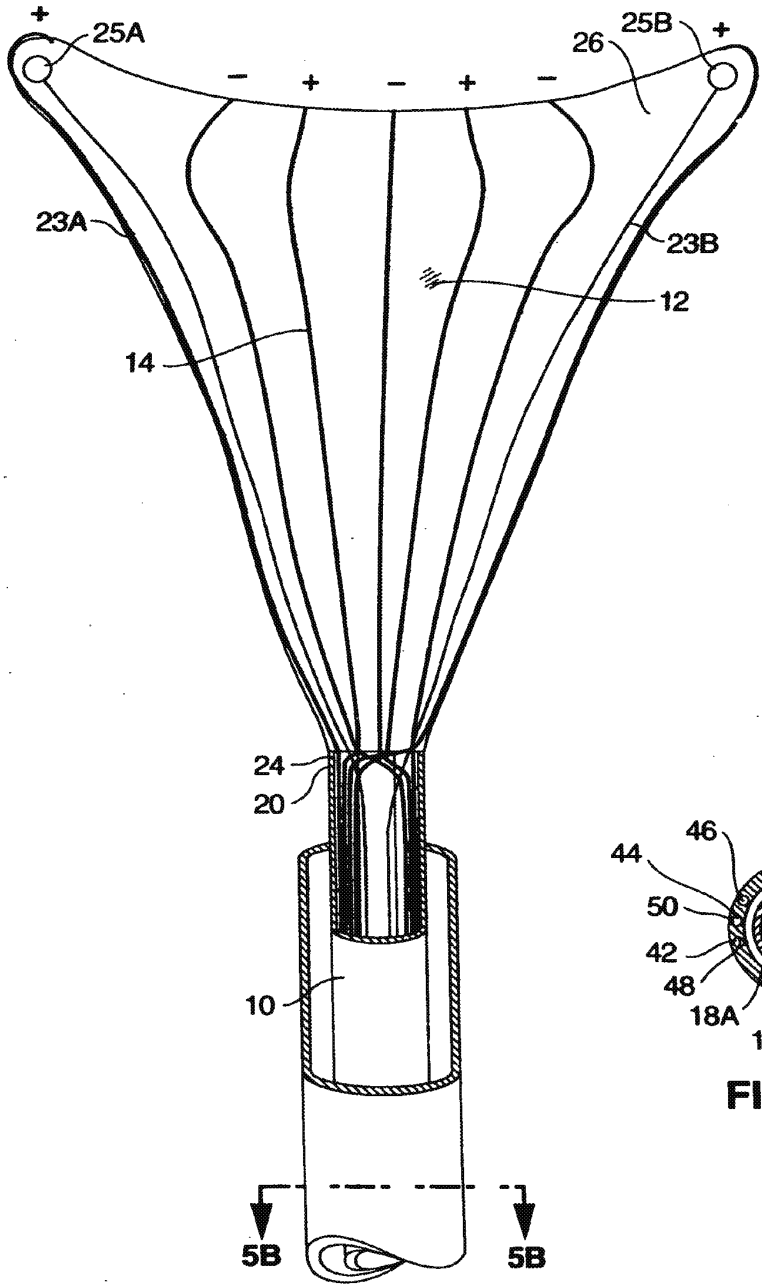
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FIG. 5A

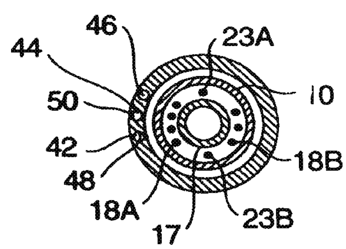
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FIG. 5B

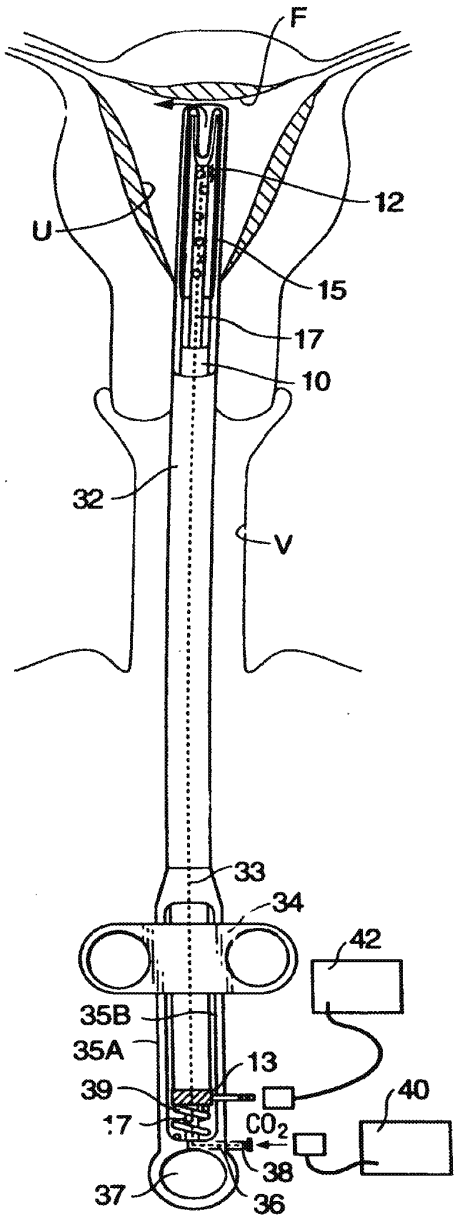
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FIG. 6

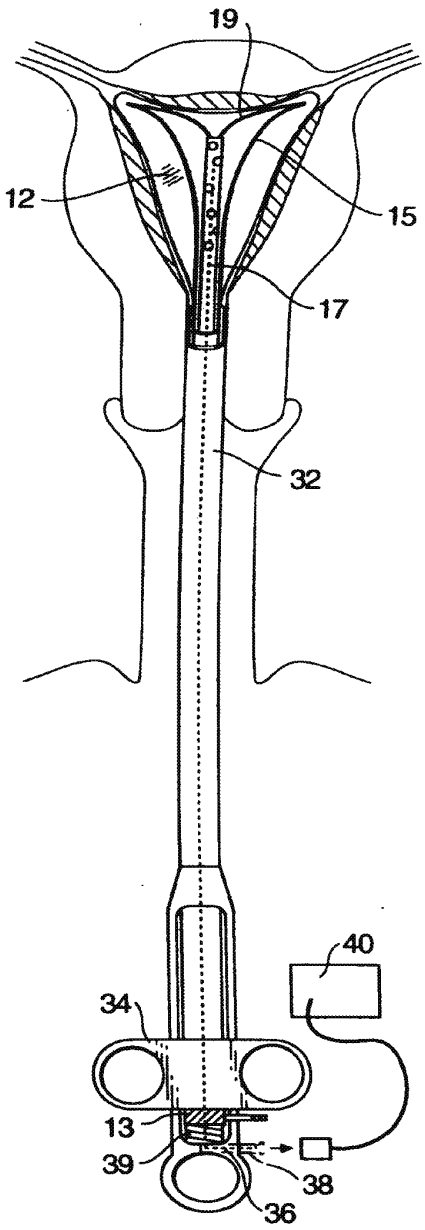
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FIG. 7

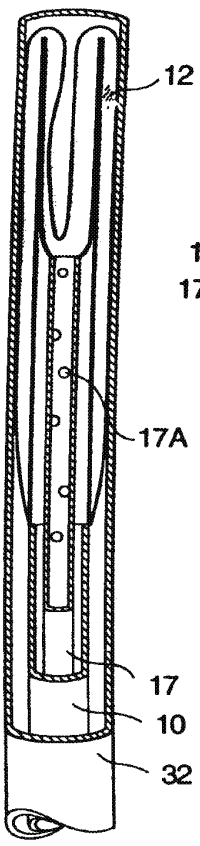

FIG. 8

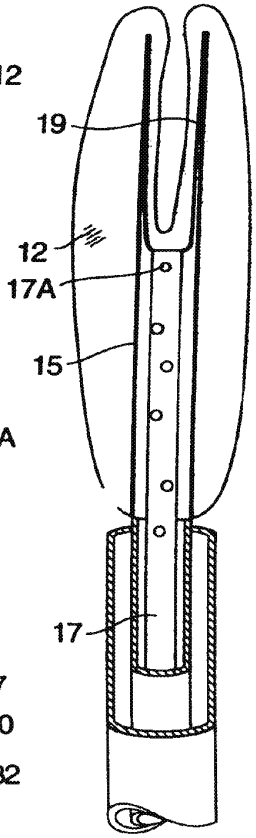

FIG. 9

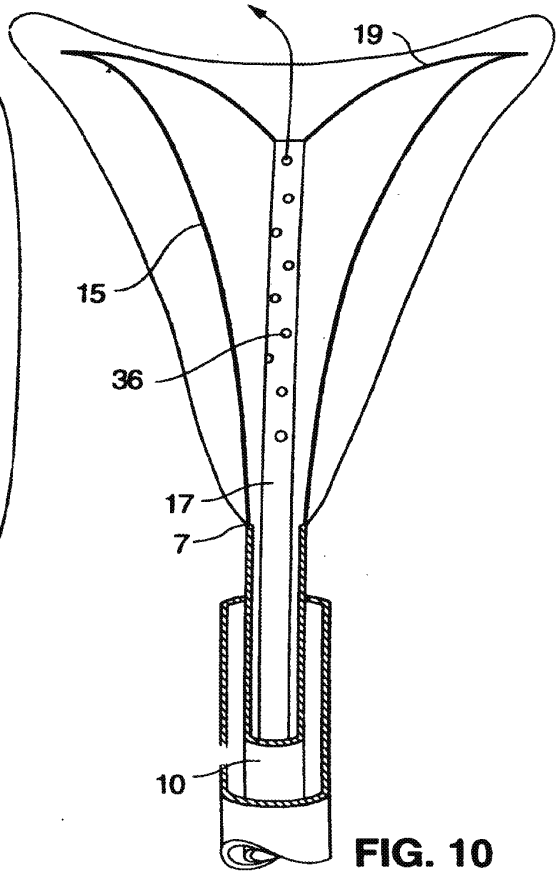

FIG. 10

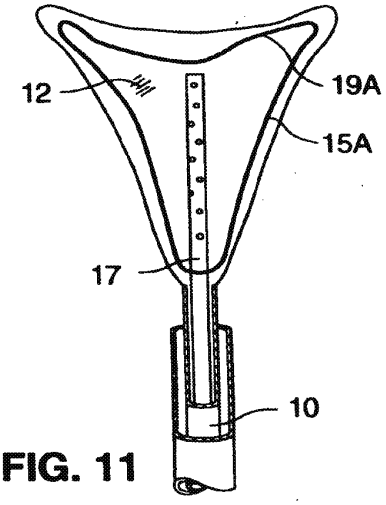

FIG. 11

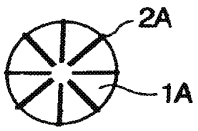

FIG. 13

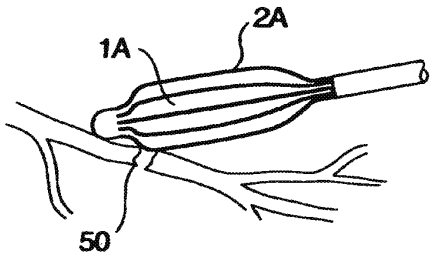

FIG. 14

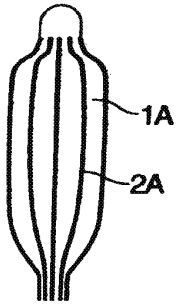

FIG. 12

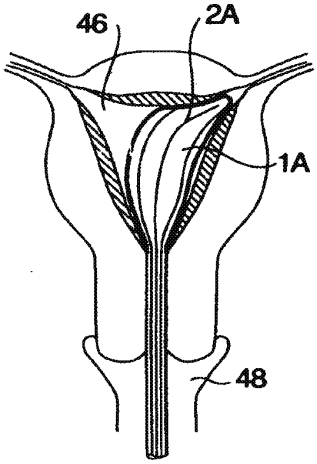

FIG. 15

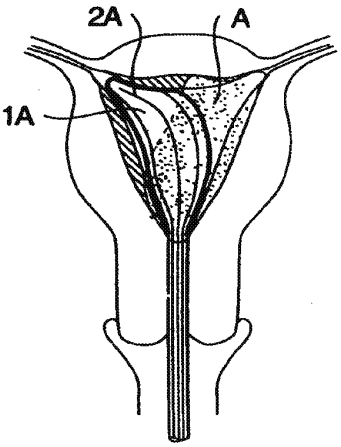

FIG. 16

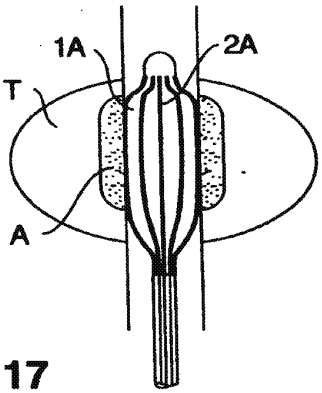

FIG. 17

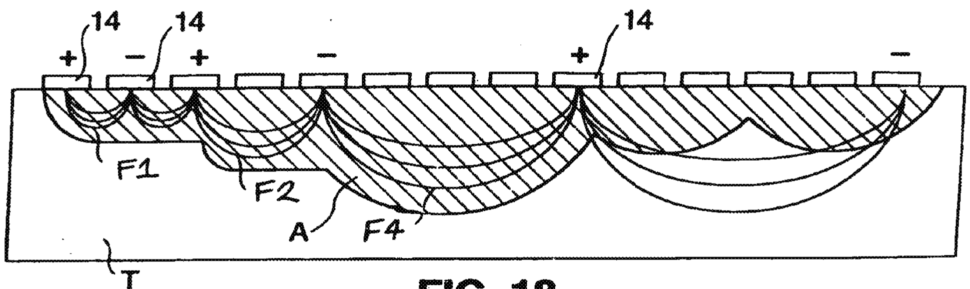

FIG. 18

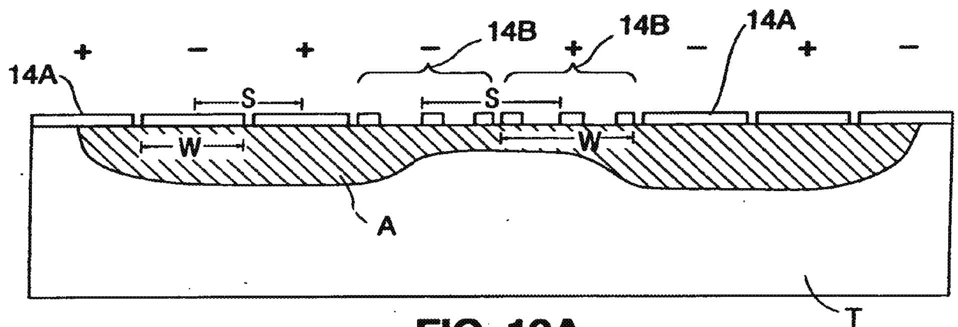

FIG. 19A

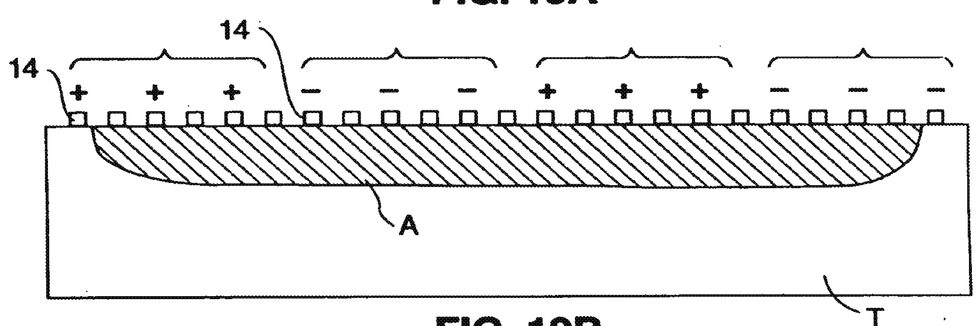

FIG. 19B

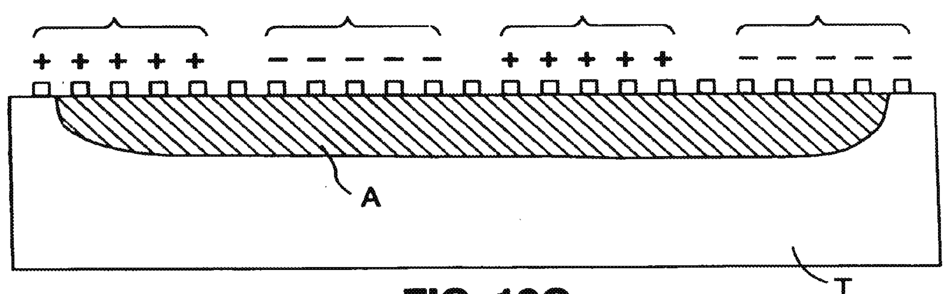

FIG. 19C

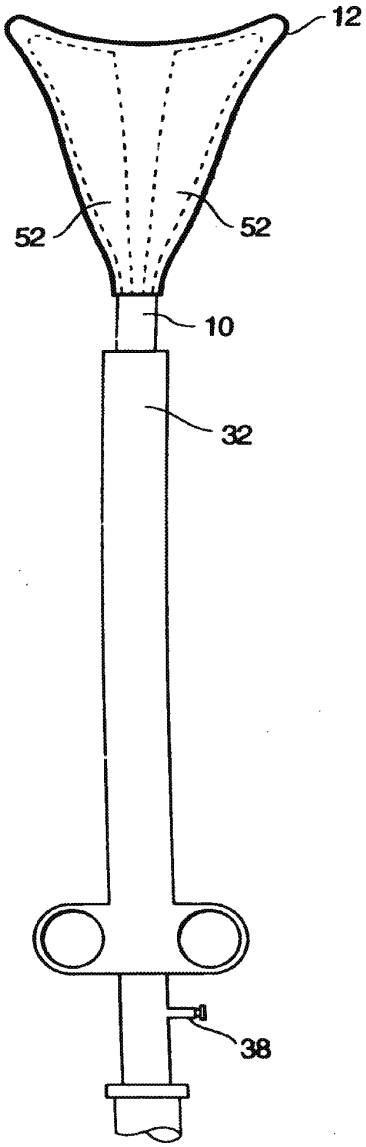

FIG. 20

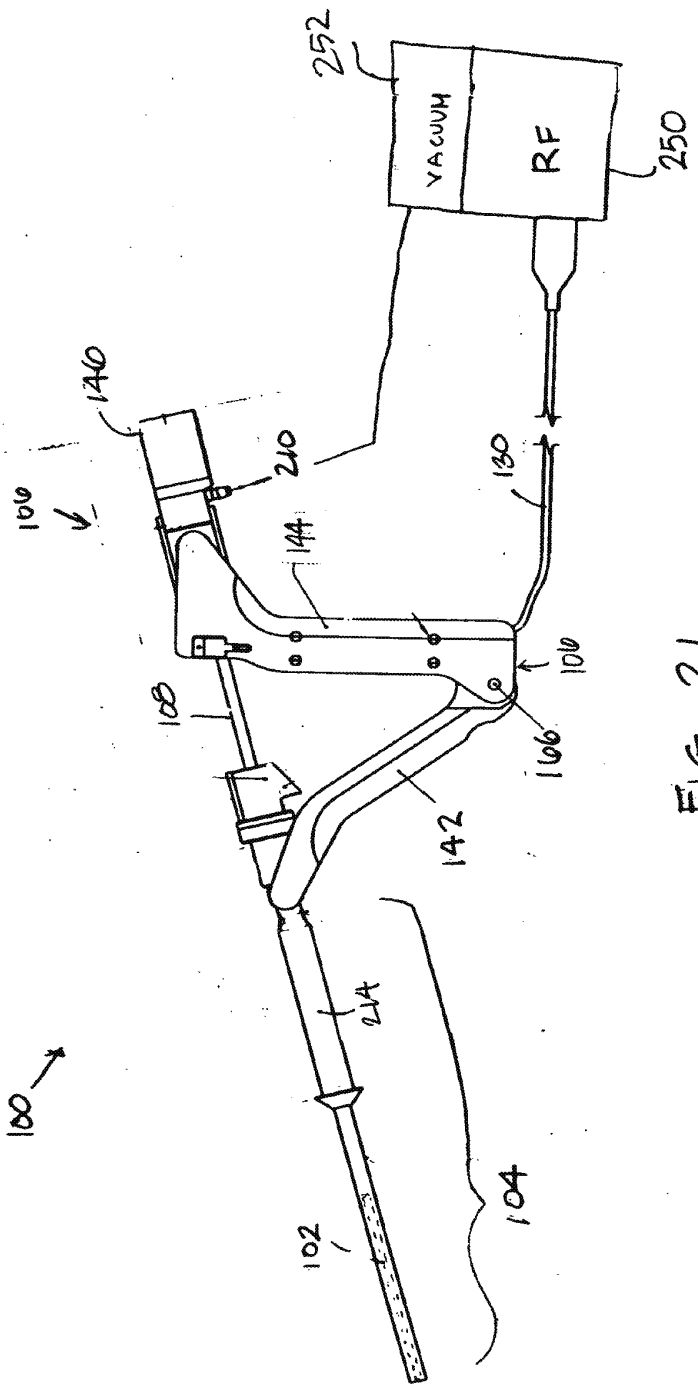

FIG. 21

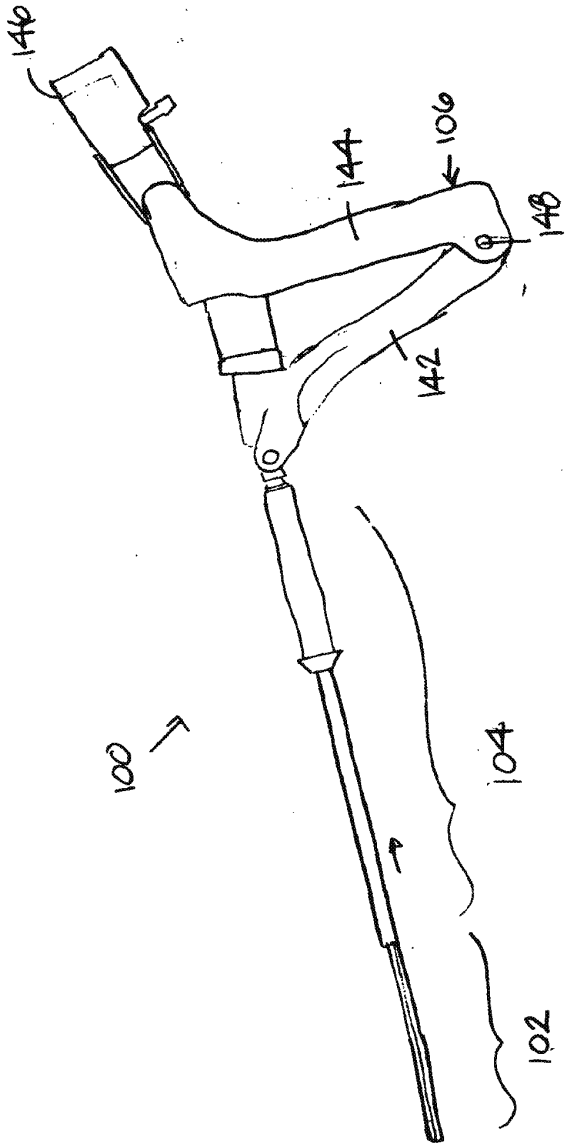

FIG. 22

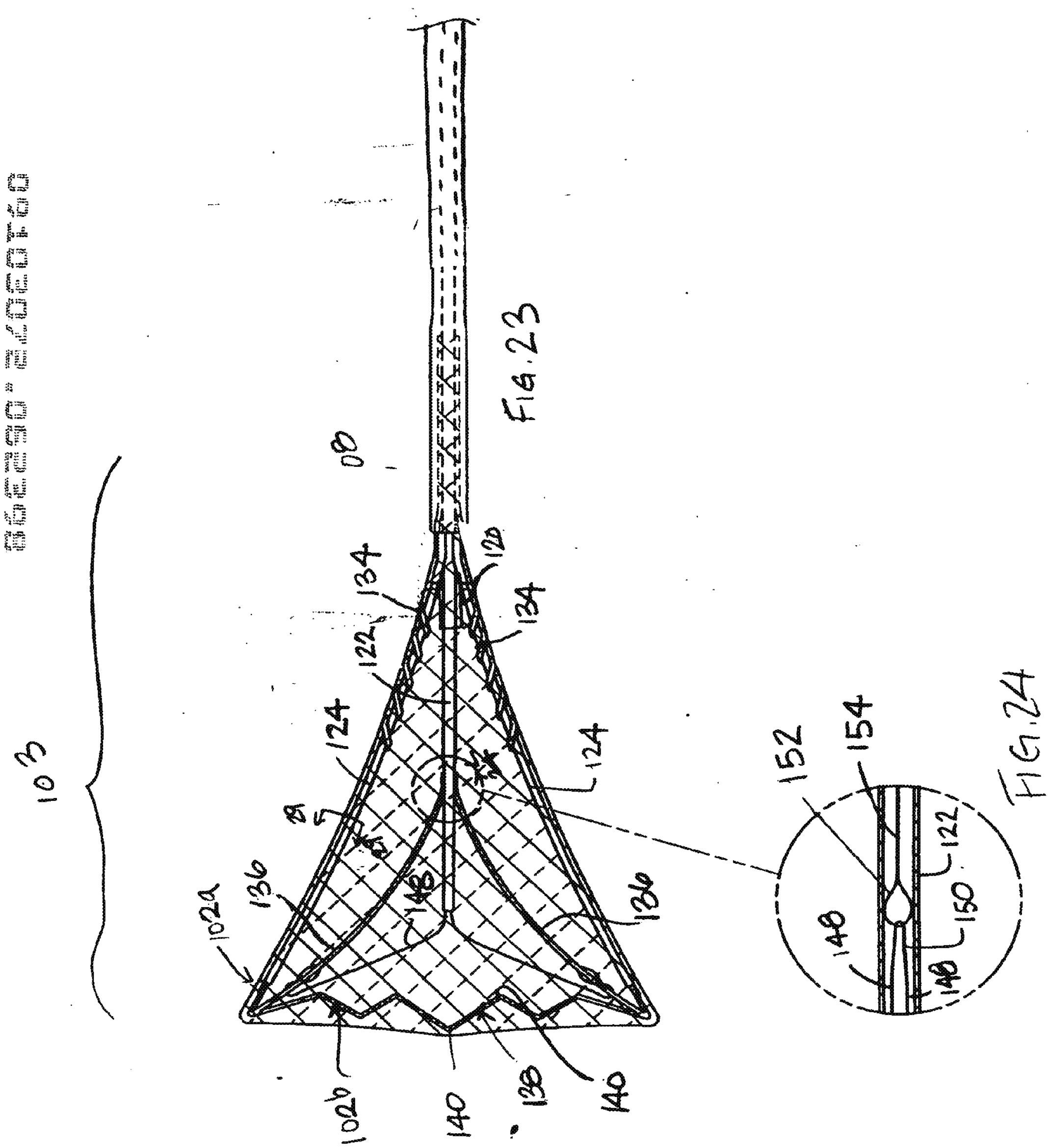

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FIG. 23
FIG. 24

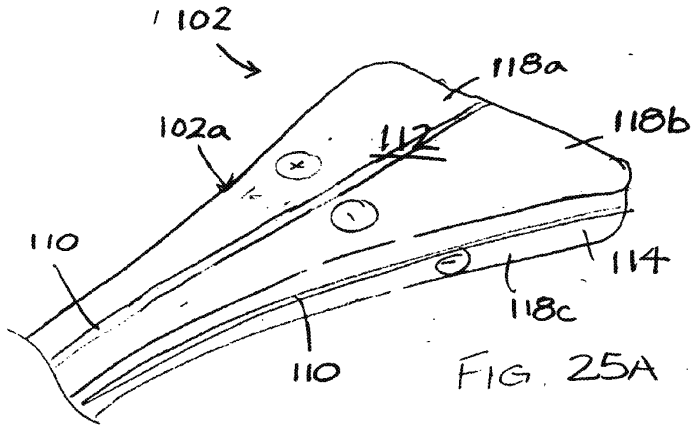


FIG. 25A

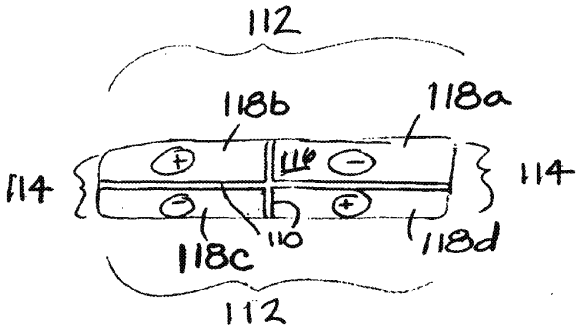


FIG 25B

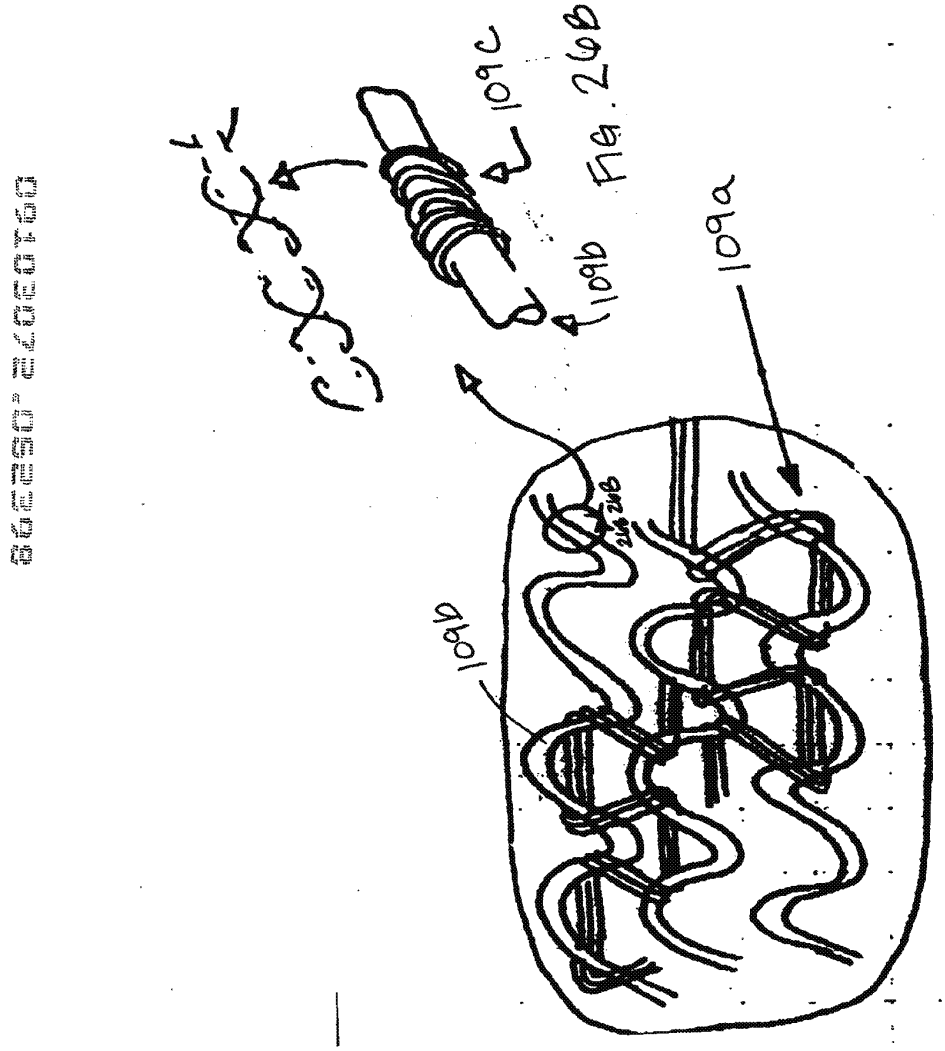


Fig. 26B

Fig. 26A

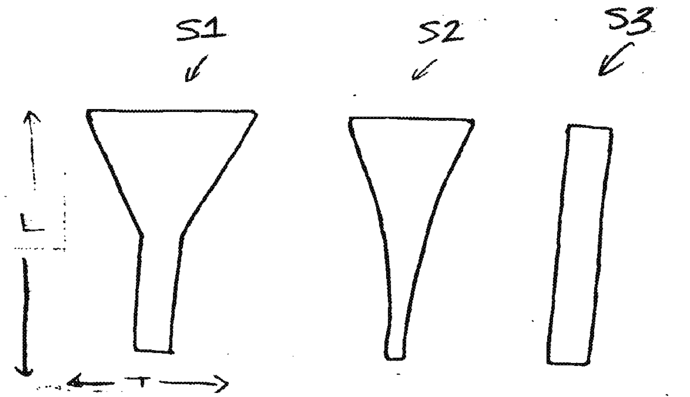


FIG. 27A FIG. 27B FIG. 27C

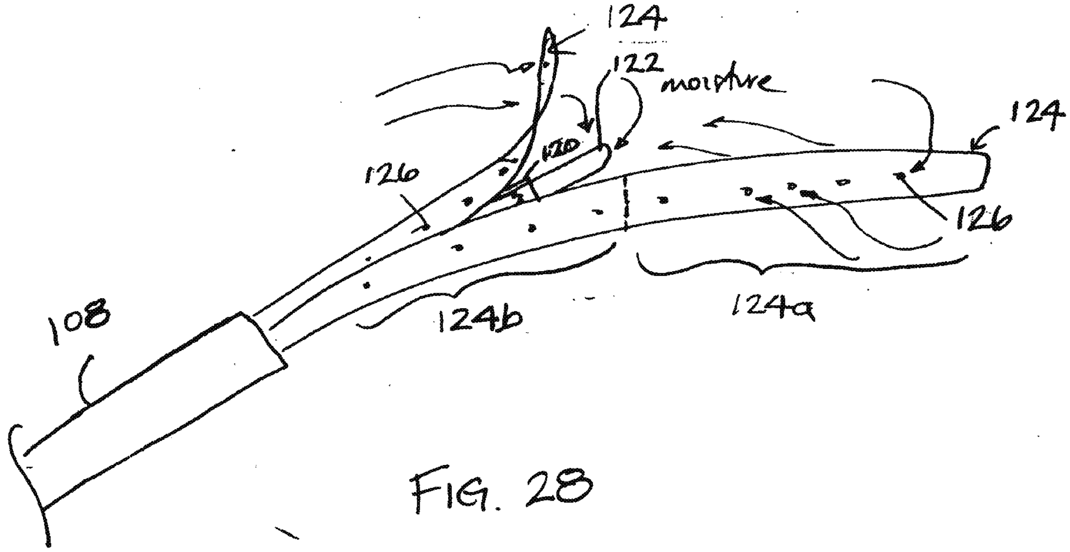


FIG. 28

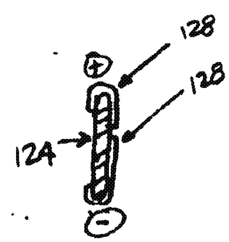


FIG 29

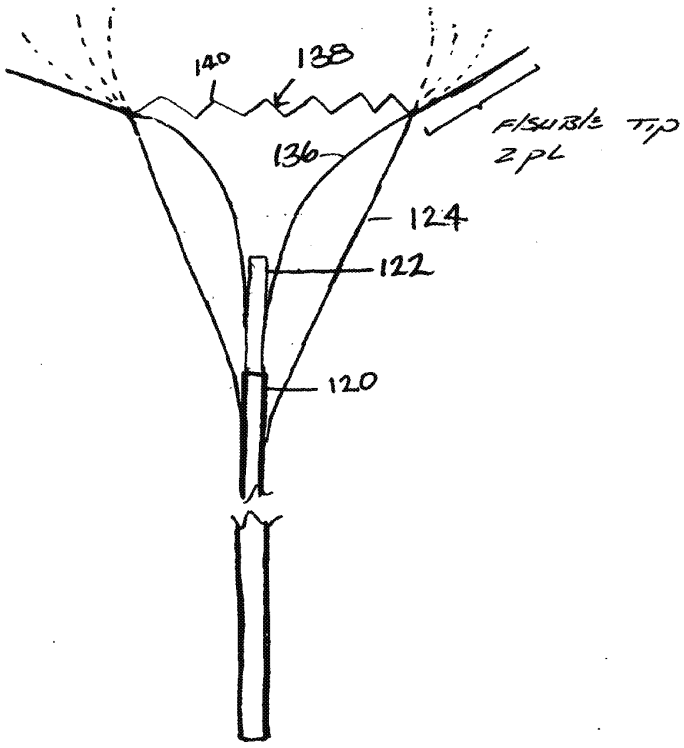


FIG. 30

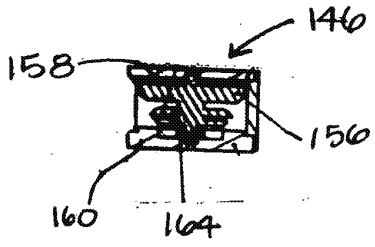


FIG. 31

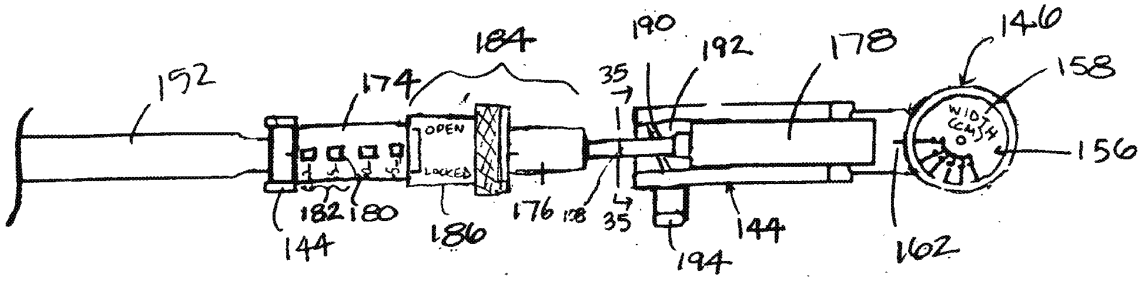


FIG. 32B

09103072.052202

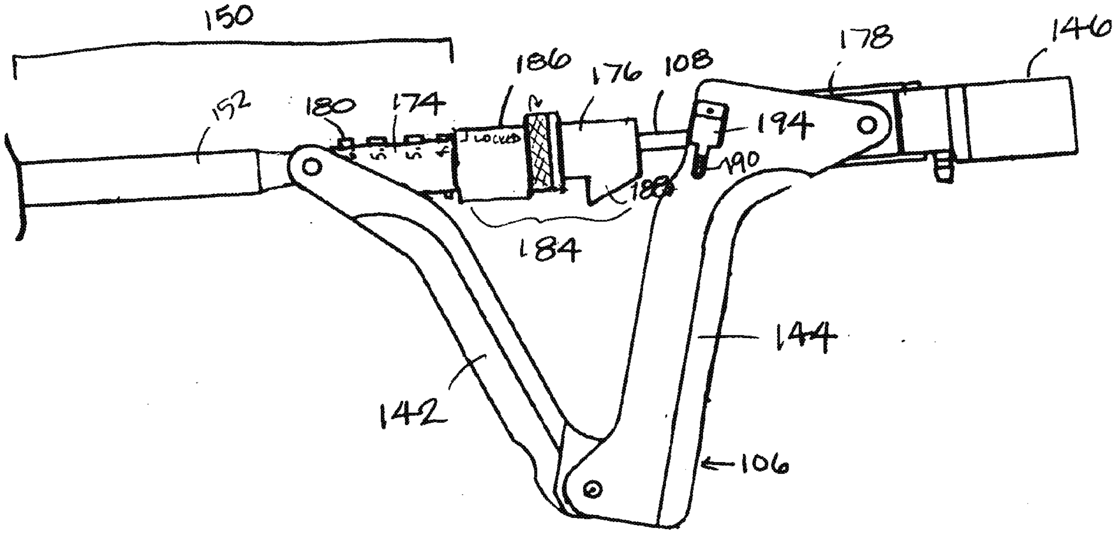


FIG. 32A

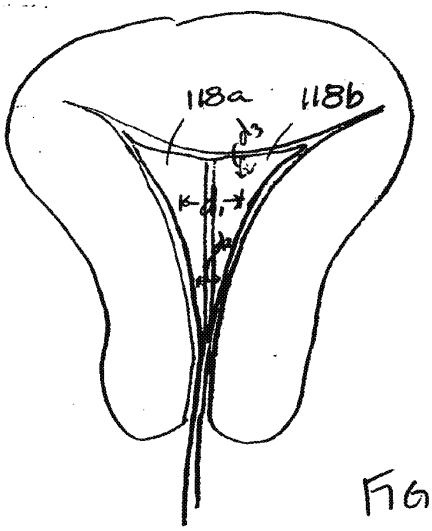


FIG 33

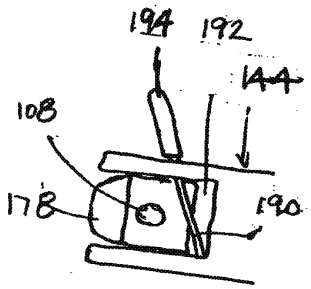


FIG. 35

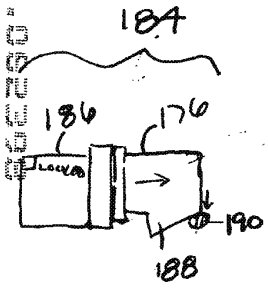


FIG 36A

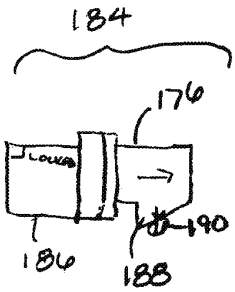


FIG 36B

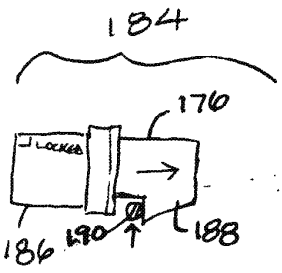


FIG 36C

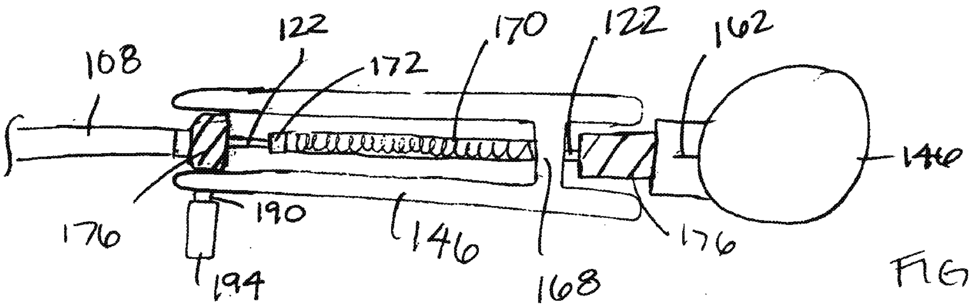


FIG. 37A

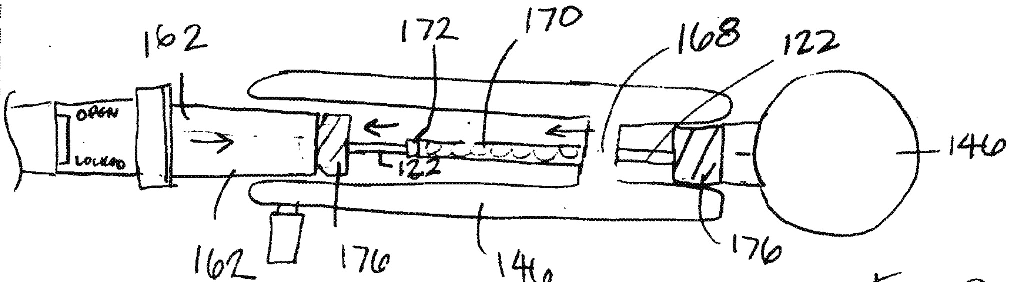
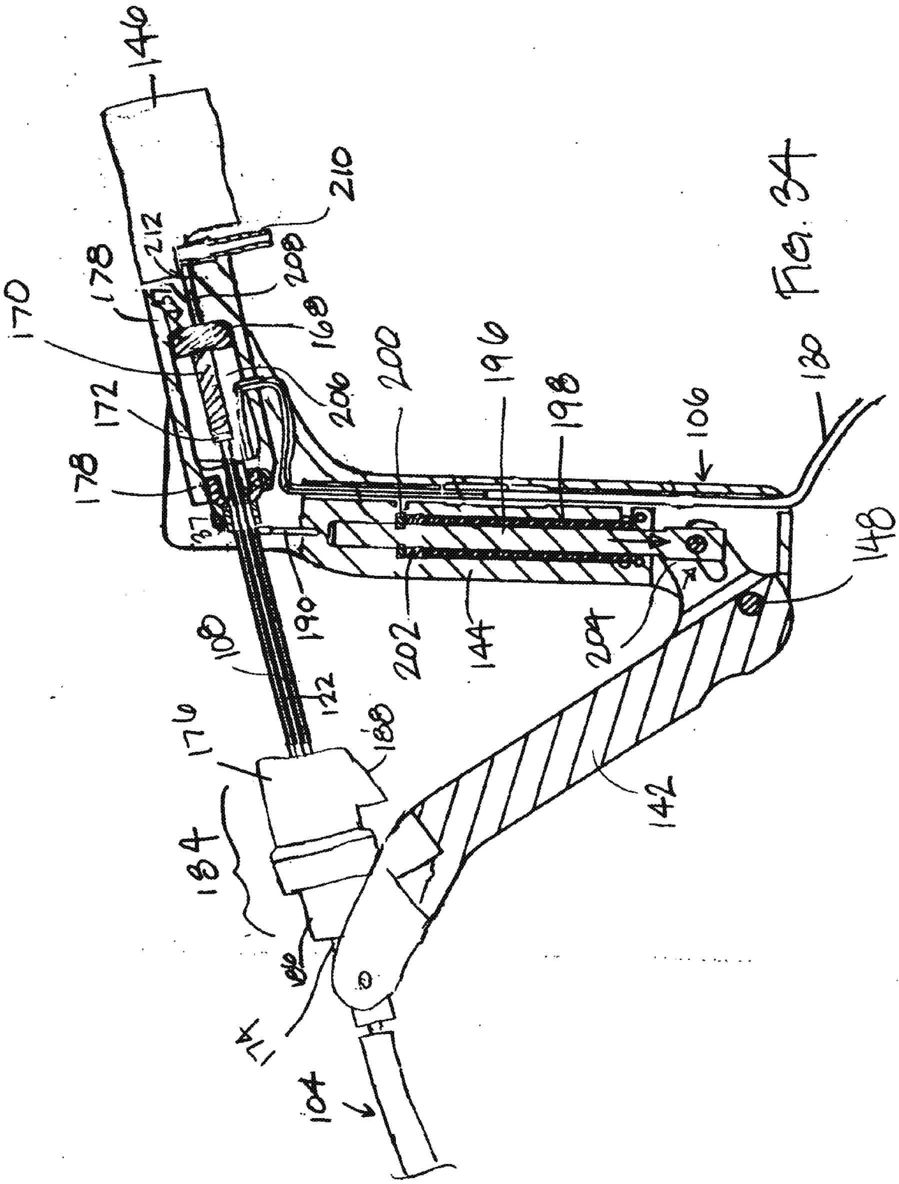


FIG. 37B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180
142
184
186
174
104

FIG. 34

PATENT APPLICATION
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A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Related Applications

This application claims the benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998, and is a Continuation in Part of copending U.S. Application No. 08/632,516, filed April 12, 1996, now U.S. Patent No. 5,769,880, issued June 23, 1998.

Field of the Invention

The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.

Background of the Invention

Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a

balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

U.S. Patent 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Patent 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

These ablation devices are satisfactory for carrying out ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only
be done by assumption.

For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF

techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation. Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C, the fluid within the tissue begins to boil and to thereby produce steam. Because ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

Summary Of The Invention

The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

Brief Description Of The Drawings

Fig. 1 is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

Fig. 2 is a front elevation view of the ablation device of Fig. 1, with the handle shown in cross-section and with the RF applicator head in an open condition.

Fig. 3 is a side elevation view of the ablation device of Fig. 2.

Fig. 4 is a top plan view of the ablation device of Fig. 2.

Fig. 5A is a front elevation view of the applicator head and a portion of the main body of the ablation device of Fig. 2, with the main body shown in cross-section.

Fig. 5B is a cross-section view of the main body taken along the plane designated 5B-5B in Fig. 5A.

Fig. 6 is a schematic representation of a uterus showing the ablation device of Fig. 1 following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

Fig. 7 is a schematic representation of a uterus showing the ablation device of Fig. 1 following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

Fig. 8 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the RF applicator head in the closed condition.

Fig. 9 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

Fig. 10 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

Fig. 11 is a cross-section view of a distal portion of an RF ablation device similar to Fig. 1 which utilizes an alternative spring member configuration for the RF applicator head.

Fig. 12 is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of Fig. 1, which utilizes an RF applicator head having a modified shape.

Fig. 13 is a top plan view of the ablation device of Fig. 12.

Fig. 14 is a representation of a bleeding vessel illustrating use of the ablation device of Fig. 12 for general bleeding control.

Figs. 15 and 16 are representations of a uterus illustrating use of the ablation device of Fig. 12 for endometrial ablation.

Fig. 17 is a representation of a prostate gland illustrating use of the ablation device of Fig. 12 for prostate ablation.

Fig. 18 is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

Figs. 19A - 19C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

Fig. 20 is a side elevation view, similar to the view of Fig. 2, showing an ablation device according to the present invention in

which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

Fig. 21 is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

Fig. 22 is a side elevation view of the ablation device of Fig. 21, showing the array in the deployed state.

Fig. 23 is a top plan view of the applicator head of the apparatus of Fig. 21.

Fig. 24 is a cross-sectional top view of the encircled region designated 24 in Fig. 23.

Fig. 25A is a perspective view of the electrode array of Fig. 23.

Fig. 25B is a distal end view of the applicator head of Fig. 30A.

Fig. 26A is a plan view of a knit that may be used to form the applicator head.

Fig. 26B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of Fig. 26A.

Figs. 27A, 27B, 27C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

Fig. 28 is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of Fig. 23.

Fig. 29 is a cross-section view of a flexure taken along the plane designated 29-29 in Fig. 23.

Fig. 30 is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

Fig. 31 is a cross-sectional side view of the bobbin portion of the apparatus of Fig. 21.

Fig. 32A is a side elevation view of the handle of the ablation device of Fig. 21.

Fig. 32B is a top plan view of the handle of the ablation device of Fig. 21. For clarity, portions of the proximal and distal grips are not shown.

Fig. 33 illustrates placement of the applicator head according to the present invention in a uterine cavity.

Fig. 34 is a side elevation view of the handle of the ablation apparatus of Fig. 21, showing portions of the apparatus in cross-section.

Fig. 35 is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated 35-35 in Fig. 32B.

Figs. 36A, 36B, and 36C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

Figs. 37A and 37B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated 37-37 in Fig. 34 and illustrating one of the load limiting

features of the second embodiment. Fig. 37A shows the condition of the compression spring before the heel member moves into abutment with frame member, and Fig 37B shows the condition of the spring after the heel member moves into abutment with the frame member.

Detailed Description

The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION" (attorney docket no. ENVS-400); and U.S. Provisional Patent Application No. _____ filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE" (attorney docket no. ENVS-500).

The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment - Structure

Referring to Figs. 1 and 2, an ablation device according to the present invention is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. Main body 4 includes a shaft 10. The RF applicator head 2 includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode

carrying means 12. An RF generator 16 is electrically connected to the electrodes 14 to provide mono-polar or bipolar RF energy to them.

Shaft 10 is an elongate member having a hollow interior. Shaft 10 is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar 13 is formed on the exterior of the shaft 10 at the proximal end. As best shown in Figs. 6 and 7, passive spring member 15 are attached to the distal end of the shaft 10.

Extending through the shaft 10 is a suction/insufflation tube 17 (Figs. 6-9) having a plurality of holes 17a formed in its distal end. An arched active spring member 19 is connected between the distal ends of the passive spring members 15 and the distal end of the suction/insufflation tube 17.

Referring to Fig. 2, electrode leads 18a and 18b extend through the shaft 10 from distal end 20 to proximal end 22 of the shaft 10. At the distal end 20 of the shaft 10, each of the leads 18a, 18b is coupled to a respective one of the electrodes 14. At the proximal end 22 of the shaft 10, the leads 18a, 18b are electrically connected to RF generator 16 via an electrical connector 21. During use, the leads 18a, 18b carry RF energy from the RF generator 16 to the electrodes. Each of the leads 18a, 18b is insulated and carries energy of an opposite polarity than the other lead.

Electrically insulated sensor leads 23a, 23b (Figs. 5A and 5B) also extend through the shaft 10. Contact sensors 25a, 25b are attached to the distal ends of the sensor leads 23a, 23b, respectively and are mounted to the electrode carrying means 12.

During use, the sensor leads 23a, 23b are coupled by the connector 21 to a monitoring module in the RF generator 16 which measures impedance between the sensors 25a, 25b. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

Referring to Fig. 5B, electrode leads 18a, 18b and sensor leads 23a, 23b extend through the shaft 10 between the external walls of the tube 17 and the interior walls of the shaft 10 and they are coupled to electrical connector 21 which is preferably mounted to the collar 13 on the shaft 10. Connector 21, which is connectable to the RF generator 16, includes at least four electrical contact rings 21a - 21d (Figs. 1 and 2) which correspond to each of the leads 18a, 18b, 23a, 23b. Rings 21a, 21b receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings 21c, 21d deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator 16.

Referring to Fig. 5A, the electrode carrying means 12 is attached to the distal end 20 of the shaft 10. A plurality of holes 24 may be formed in the portion of the distal end 20 of the shaft which lies within the electrode carrying means 12.

The electrode carrying means 12 preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in Figs. 1 through 11 has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means 12 shown in these figures includes horn regions 26 which during use are positioned within the cornual

regions of the uterus and which therefore extend towards the fallopian tubes.

Electrode carrying means 12 is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

Electrodes 14 are preferably attached to the outer surface of the electrode carrying means 12, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means 12 by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means 12 is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

For example, by using 3-6 mm spacing and an electrode width of approximately 0.5 - 2.5 mm, delivery of approximately 20 - 40 watts over a 9-16 cm^2 target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2 - 3 mm when the active electrode surfaces covers less than 1 % of the target tissue area. This can be better understood with reference to Fig. 19A, in which high surface density electrodes are designated 14a and low surface density electrodes are designated 14b. For

purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in Fig. 19A.

As is apparent from Fig. 19A, the electrodes 14a, which have more active area in contact with the underlying tissue T, produce a region of ablation A1 that extends more deeply into the tissue T than the ablation region A2 produced by the low density electrodes 14b, even though the electrode spacings and widths are the same for the high and low density electrodes.

Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm^2 and a power of 20 - 40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1 - 2 mm	1 - 3 mm
1 - 2.5 mm	3 - 6 mm	5 - 7 mm
1 - 4.5 mm	8 - 10 mm	8 - 10 mm

Examples of electrode widths, having spacings with less than 1 % active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm^2 and a power of 20 - 40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1 - 2 mm	0.5 - 1 mm
1 - 2.5 mm	3 - 6 mm	2 - 3 mm
1 - 4.5 mm	8 - 10 mm	2 - 3 mm

Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

In the preferred embodiment, the preferred electrode spacing is approximately 8 - 10 mm in the horn regions 26 with the active electrode surfaces covering approximately 1% of the target region. Approximately 1 - 2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated 28) and approximately 3 - 6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

The RF generator 16 may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to Fig. 18.

Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes

may be arranged in any pattern to provide ablation to desired depths.

Referring to Figs. 6 and 7, an introducer sheath 32 facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath 32 is a tubular member which is telescopically slidable over the shaft 10. The sheath 32 is slidable between a distal condition, shown in Fig. 6, in which the electrode carrying means 12 is compressed inside the sheath, and a proximal condition in which the sheath 32 is moved proximally to release the electrode carrying means from inside it (Fig. 7). By compressing the electrode carrying means 12 to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

A handle 34 attached to the sheath 32 provides finger holds to allow for manipulation of the sheath 32. Handle 34 is slidably mounted on a handle rail 35 which includes a sleeve 33, a finger cutout 37, and a pair of spaced rails 35a, 35b extending between the sleeve 33 and the finger cutout 37. The shaft 10 and sheath 32 slidably extend through the sleeve 33 and between the rails 35a, 35b. The tube 17 also extends through the sleeve 33 and between the rails 35a, 35b, and its proximal end is fixed to the handle rail 35 near the finger cutout 37.

A compression spring 39 is disposed around the proximal most portion of the suction/insufflation tube 17 which lies between the rails 35a, 35b. One end of the compression spring 39 rests against the collar 13 on the shaft 10, while the opposite end of the compression spring rests against the handle rail 35. During

use, the sheath 32 is retracted from the electrode carrying means 12 by squeezing the handle 34 towards the finger cutout 37 to slide the sheath 32 in the distal direction. When the handle 34 advances against the collar 13, the shaft 10 (which is attached to the collar 13) is forced to slide in the proximal direction, causing compression of the spring 39 against the handle rail 35. The movement of the shaft 10 relative to the suction/insufflation tube 17 causes the shaft 10 to pull proximally on the passive spring member 15. Proximal movement of the passive spring member 15 in turn pulls against the active spring member 19, causing it to move to the opened condition shown in Fig. 7. Unless the shaft is held in this retracted condition, the compression spring 39 will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

The amount by which the springs 15, 19 are spread may be controlled by manipulating the handle 34 to slide the shaft 10 (via collar 13), proximally or distally. Such sliding movement of the shaft 10 causes forceps-like movement of the spring members 15, 19.

A flow pathway 36 is formed in the handle rail 35 and is fluidly coupled to a suction/insufflation port 38. The proximal end of the suction/insufflation tube 17 is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38. For example, suction may be applied to the fluid port 38 using a

suction/insufflation unit 40. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube 17 via the port 38. The insufflation gas travels through the tube 17, through the holes 17a, and into the uterine cavity through the permeable electrode carrying member 12.

If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen 42, 44, and 46 may be formed in the walls of the introducer sheath 32 as shown in Fig. 5B. An imaging conduit, such as a fiberoptic cable 48, extends through lumen 42 and is coupled via a camera cable 43 to a camera 45. Images taken from the camera may be displayed on a monitor 56. An illumination fiber 50 extends through lumen 44 and is coupled to an illumination source 54. The third lumen 46 is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

Because during use it is most desirable for the electrodes 14 on the surface of the electrode carrying means 12 to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means 12 may be provide to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

For example, referring to Fig. 11, alternative spring members 15a, 19a may be attached to the shaft 10 and biased such that,

when in a resting state, the spring members are positioned in the fully resting condition shown in Fig. 11. Such spring members would spring to the resting condition upon withdrawal of the sheath 32 from the RF applicator head 2.

Alternatively, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in Fig. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52. After insertion of the apparatus into the organ and following retraction of the sheath 32, the balloons 52 would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port 38 using an apparatus similar to the suction/insufflation apparatus 40.

Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end 22 of the suction/insufflation tube 17. Application of suction using the suction/insufflation device 40 would draw the organ tissue towards the electrode carrying means 12 and thus into better contact with the electrodes 14.

Figs. 12 and 13 show an alternative embodiment of an ablation device according to the present invention. In the alternative embodiment, an electrode carrying means 12a is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (Fig. 14),

tissue ablation in the prostate gland (Fig. 17), and also intrauterine ablation (Figs. 15 and 16).

First Exemplary Embodiment - Operation

Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

Referring to Fig. 1, the device is initially configured for use by positioning the introducer sheath 32 distally along the shaft 10, such that it compresses the electrode carrying means 12 within its walls.

At this time, the electrical connector 21 is connected to the RF generator 16, and the fiberoptic cable 48 and the illumination cable 50 are connected to the illumination source, monitor, and camera, 54, 56, 45. The suction/insufflation unit 40 is attached to suction/insufflation port 38 on the handle rail 35. The suction/insufflation unit 40 is preferably set to deliver carbon dioxide at an insufflation pressure of 20 - 200 mmHg.

Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in Fig. 6, until the distal end of the introducer sheath 32 contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube 17 via the port 38, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera 45 and monitor 56) the internal cavities using images detected by a fiberoptic cable 48 inserted through lumen 42. If, upon observation, the physician determines that a tissue biopsy or other procedure is

needed, the required instruments may be inserted into the uterine cavity via the instrument channel 46.

Following insertion, the handle 34 is withdrawn until it abuts the collar 13. At this point, the sheath 32 exposes the electrode carrying member 12 but the electrode carrying member 12 is not yet fully expanded (see Fig 9), because the spring members 15, 19 have not yet been moved to their open condition. The handle 34 is withdrawn further, causing the shaft 10 to move proximally relative to the suction/insufflation tube 17, causing the passive spring members 15 to pull the active spring members 19, causing them to open into the opened condition shown in Fig. 10.

The physician may confirm proper positioning of the electrode carrying member 12 using the monitor 56, which displays images from the fiberoptic cable 48.

Proper positioning of the device and sufficient contact between the electrode carrying member 12 and the endometrium may further be confirmed using the contact sensors 25a, 25b. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20 - 180 ohm, depending on the water content of the endometrial lining.

The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member 12, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors 25a, 25b that there is sound contact

between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

Next, insufflation is terminated. Approximately 1 - 5 cc of saline may be introduced via suction/insufflation tube 17 to initially wet the electrodes and to improve electrode electrical contact with the tissue. After introduction of saline, the suction/insufflation device 40 is switched to a suctioning mode. As described above, the application of suction to the RF applicator head 2 via the suction/insufflation tube 17 collapses the uterine cavity onto the RF applicator head 2 and thus assures better contact between the electrodes and the endometrial tissue.

If the generally tubular apparatus of Figs. 12 and 13 is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. Figs. 15 and 16.

Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in Fig. 5a, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F1, F2 and F4 in Fig. 18, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in Fig. 18, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F2 which results from

energization of electrodes having a non-energized electrode between them, or pattern F4 which results from energization of electrodes having two non-energized electrodes between them).

Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see Fig. 19A). Referring to Fig. 19B, if multiple, closely spaced, electrodes 14 are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in Fig. 19B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

As another example, shown in Fig. 19C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member 12 and is thereby drawn away from the electrodes. The moisture may pass through the holes 17a in the suction/insufflation tube 17 and leave the suction/insufflation tube 17 at its proximal end via port 38 as shown in Fig. 7. Moisture removal from the ablation site may be further facilitated by the

application of suction to the shaft 10 using the suction/insufflation unit 40.

Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

Once the process has self terminated, 1 - 5 cc of saline can be introduced via suction/insufflation tube 17 and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction/insufflation device 40 is then switched to provide insufflation of carbon dioxide at a pressure of 20 - 200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head 2 and to thus ease the closing of the RF applicator head. The RF applicator head 2 is moved to the closed position by sliding the handle 34 in a distal direction to fold the spring members 15, 19 along the axis of the device and to cause the introducer sheath 32 to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor 56. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment - Structure

A second embodiment of an ablation device 100 in accordance with the present invention is shown in Figs. 21 - 37B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and

second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

Referring to Figs. 21 and 22, the second embodiment includes an RF applicator head 102, a sheath 104, and a handle 106. As with the first embodiment, the applicator head 102 is slidably disposed within the sheath 104 (Fig. 21) during insertion of the device into the uterine cavity, and the handle 106 is subsequently manipulated to cause the applicator head 102 to extend from the distal end of the sheath 104 (Fig. 22) and to expand into contact with body tissue (Fig. 33).

RF Applicator Head

Referring to Fig. 23, in which the sheath 104 is not shown for clarity, applicator head 102 extends from the distal end of a length of tubing 108 which is slidably disposed within the sheath 104. Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.

Referring to Figs. 25A and 25B, the array 102a of applicator head 102 is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in Figs. 26A and 26B) is formed of three monofilaments of nylon 109a knitted together with single yarns of spandex 109b. Each yarn of spandex 109b has a double helix 109c of five nylon monofilaments coiled around it.

This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially elongates from its coiled configuration.

One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere. Next, the insulating regions 110 (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface,

is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

The mesh may be configured in a variety of shapes, including but not limited to the triangular shape S1, parabolic S2, and rectangular S3 shapes shown in Figs. 27A, 27B and 27C, respectively.

Turning again to Figs. 25A and 25B, when in its expanded state, the array 102a includes a pair of broad faces 112 spaced apart from one another. Narrower side faces 114 extend between the broad faces 112 along the sides of the applicator head 102, and a distal face 116 extends between the broad faces 112 at the distal end of the applicator head 102.

Insulating regions 110 are formed on the applicator head to divide the mesh into electrode regions. The insulated regions 110 are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

The array may be divided by the insulated regions 110 into a variety of electrode configurations. In a preferred configuration the insulating regions 110 divide the applicator head into four electrodes 118a - 118d by creating two electrodes on each of the broad faces 112. To create this four-electrode pattern, insulating regions 110 are placed longitudinally along each of the broad faces 112 as well as along the length of each of the faces 114, 116. The electrodes 118a-118d are used for ablation and, if desired, to measure tissue impedance during use.

Deflecting mechanism 102b and its deployment structure is enclosed within electrode array 102a. Referring to Fig. 23, external hypotube 120 extends from tubing 108 and an internal hypotube 122 is slidably and co-axially disposed within hypotube 120. Flexures 124 extend from the tubing 108 on opposite sides of external hypotube 120. A plurality of longitudinally spaced apertures 126 (Fig. 28) are formed in each flexure 124. During use, apertures 126 allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube 120 using a vacuum source fluidly coupled to hypotube 120.

Each flexure 124 preferably includes conductive regions that are electrically coupled to the array 102a for delivery of RF energy to the body tissue. Referring to Fig. 29, strips 128 of copper tape or other conductive material extend along opposite surfaces of each flexure 124. Each strip 128 is electrically insulated from the other strip 128 by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips 128 and extend through tubing 108 (Fig. 23) to an electrical cord 130 (Fig. 21) which is attachable to the RF generator.

During use, one strip 128 on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple

conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures 124 may instead be used for electrically connecting the electrode array to the source of RF energy.

It is important to ensure proper alignment between the conductive regions of the flexures 124 (e.g. copper strips 128) and the electrodes 118a - 118d in order to maintain electrical contact between the two. Strands of thread 134 (which may be nylon) (Fig. 23) are preferably sewn through the array 102a and around the flexures 124 in order to prevent the conductive regions 128 from slipping out of alignment with the electrodes 118a - 118d. Alternate methods for maintaining contact between the array 102a and the conductive regions 128 include using tiny bendable barbs extending between the flexures 124 and the array 102a to hook the array to the conductive regions 128, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

Referring again to Fig. 23, internal flexures 136 extend laterally and longitudinally from the exterior surface of hypotube 122. Each internal flexure 136 is connected at its distal end to one of the flexures 124 and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. Transverse ribbon 138 is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in Fig. 23 and such that when in a compressed condition it is folded along the plurality of creases 140 that extend along its length. Flexures 124,

136 and ribbon 138 are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

The deflecting mechanism is preferably configured such that the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections 124a (Fig. 28) of the flexures from a material that is more flexible than the proximal sections 124b. For example, flexures 124 may be provided to have proximal sections formed of a material having a modulus of approximately 28 x 10^6 psi and distal sections having a durometer of approximately 72D.

Alternatively, referring to Fig. 30, the flexures 124 may be joined to the internal flexures 136 at a location more proximal than the distal tips of the flexures 124, allowing them to move more freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in Fig. 30). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

The deflecting mechanism formed by the flexures 124, 136, and ribbon 138 forms the array into the substantially triangular shape shown in Fig. 23, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head.

This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

Measurement Device

The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge 146 (Fig. 21). The measurement device utilizes non-conductive (e.g. nylon) suturing threads 148 that extend from the hypotube 122 and that have distal ends attached to the distal portion of the deflecting mechanism (Fig. 23). As shown in Fig. 24, threads 148 are preferably formed of a single strand 150 threaded through a wire loop 152 and folded over on itself. Wire loop 152 forms the distal end of an elongate wire 154 which may be formed of stainless steel or other wire.

Referring to Fig. 31, wire 154 extends through the hypotube 122 and is secured to a rotatable bobbin 156. The rotatable bobbin 156 includes a dial face 158 preferably covered in a clear plastic. As can be seen in Fig. 32, dial face 158 includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing 160 and a corresponding marker line 162 is printed on the gauge housing. A torsion spring 164 provides rotational resistance to the bobbin 156.

Expansion of the applicator head 102 during use pulls threads 148 (Fig. 23) and thus wire 154 (Fig. 24) in a distal direction. Wire 154 pulls against the bobbin 156 (Fig. 31), causing it to rotate.

Rotation of the bobbin positions one of the calibration markings on dial face 158 into alignment with the marker line 162 (Fig. 32B) to indicate the distance between the distal tips of flexures 124 and thus the uterine width.

The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures 124 and to electronically transmit the uterine width to the RF generator.

Control of Ablation Depth

The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2 - 3 mm for the cervical os and the cornual regions, and approximately 7 - 8 mm in the main body of the uterus where the endometrium is substantially thicker.

As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a

given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can been seen with reference to Fig. 33 that the center to center distance d1 between the electrodes 118a, 118b is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d2 between electrodes 118a, 118b is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d3 extend between top and bottom electrodes 118b, 118c and 118a, 118d and again contribute to shallower ablation.

Naturally, because the array 102a expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array 102a vary. One embodiment of the array 102a includes a

range of widths of at least approximately 2.5 - 4.5 cm, a range of lengths of at least approximately 4 -6 cm, and a density of approximately 35% - 45%.

The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head 102 and displayed on gauge 146. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following relationship:

$$P = L \times W \times 5.5$$

Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

Handle

Referring again to Figs. 21 and 22, the handle 106 of the RF ablation device according to the second embodiment includes a distal grip section 142 and a proximal grip section 144 that are pivotally attached to one another at pivot pin 166.

The proximal grip section 144 is coupled to the hypotube 122 (Fig. 23) via yoke 168, overload spring 170 and spring stop 172, each of which is shown in the section view of Fig. 34. The distal grip section 142 is coupled to the external hypotube 120 via male and female couplers 174, 176 (see Figs. 32A and 32B). Squeezing the grip sections 142, 144 towards one another thus causes relative movement between the external hypotube 120 and the internal hypotube 122. This relative sliding movement results in deployment of the deflecting mechanism 102b from the distal end of the sheath and expansion of the array 102a to its expanded state.

Referring to Figs. 32A and B, rack 180 is formed on male coupler 174 and calibration markings 182 are printed adjacent the rack 180. The calibration markings 182 correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

A sliding collar 184 is slidably disposed on the tubing 108 and is slidable over male coupler 174. Sliding collar 184 includes a rotating collar 186 and a female coupler 176 that includes a wedge-shaped heel 188. A locking spring member 190 (Figs. 32B and 35) extends across an aperture 192 formed in the proximal grip 144 in alignment with the heel 188. When the distal and proximal handle sections are squeezed together to deploy the array, the heel 188 passes into the aperture 192. Its inclined lower surface gradually depresses the spring member 190 as the heel moves further into the aperture 192. See Figs. 36A and 36B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See Fig. 36C.

A release lever 194 (Fig. 35) is attached to the free end of the spring member 190. To disengage the spring lock, release lever 194 is depressed to lower spring member 190 so that the inclined heel can pass over the spring member and thus out of the aperture 192.

Referring again to Figs. 32A and 32B, sliding collar 184 is configured to allow the user to limit longitudinal extension of the array 102a to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler 174 relative to the female coupler 176 using the rotating collar 186 to lock and unlock the female coupler from the rack 180 and the male coupler 174. Locking the female coupler to the rack 180 and male coupler 174 will limit extension of the array to approximately the

predetermined uterine length, as shown on the calibration markings 182.

Once the uterine length has been measured using a conventional sound, the user positions sliding collar 184 adjacent to calibration marks 182 corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section 186 to engage its internally positioned teeth with the rack 180. This locks the longitudinal position of the heel 188 such that it will engage with the spring member 190 on the proximal grip when the array has been exposed to the length set by the sliding collar.

The handle 106 includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array 102a. One of the spring assemblies controls movement of the grips 142, 144 to automatically stow the array 102a into the sheath 104 when the user stops squeezing the grips 142, 144 towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures 124 to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism 102b.

Fig. 34 shows the distal and proximal grips 142 and 144 in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel 196 that is slidably disposed within the proximal grip 144. A compression spring 198 surrounds a portion of the return mandrel 196, and a retaining ring 200 is attached to the mandrel 196 above the spring 198. A spring stop 202 is disposed between the spring 198 and the retaining ring.

The lowermost end of the return mandrel 196 is pivotally engaged by a coupling member 204 on distal grip 142. Relative movement of the grips 142, 144 towards one another causes the coupling member 204 to pull the return member downwardly with the proximal grip 144 as indicated by arrows. Downward movement of the mandrel 196 causes its retaining ring 200 and spring stop 202 to bear downwardly against the compression spring 198, thereby providing a movement which acts to rotate the grips 142, 144 away from one another. When tension against the grips 142, 144 is released (assuming that heel 188 is not locked into engagement with spring member 190) the grips rotate apart into the opened position as the compression spring 198 returns to the initial state, stowing the applicator head inside the sheath.

The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member 178 disposed over yoke 168, which is pivotally attached to proximal grip 144. Tubing 108 extends from the array 102a (see Fig. 23), through the sheath 104 and is fixed at its proximal end to the frame member 178. Hypotube 122 does not terminate at this point but instead extends beyond the proximal end of tubing 108 and through a window 206 in the frame member. Its proximal end 208 is slidably located within frame member 178 proximally of the window 206 and is fluidly coupled to a vacuum port 210 by fluid channel 212. Hypotube 120 terminates within the frame. Its proximal end is fixed within the distal end of the frame.

A spring stop 214 is fixed to a section of the hypotube within the window 206, and a compression spring 170 is disposed around

the hypotube between the spring stop 172 and yoke 168. See Figs. 32B and 34.

When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath 104 from the array 102a. Referring to Figs. 37A and 37B, this motion continues until female coupler 176 contacts and bears against frame member 178. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120. An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array. Compression spring 170 acts to limit the force developed by the operator against hypotubes 120, 122, thus limiting the force of flexures 124, 136 acting on the array and the target tissue surrounding the array.

Referring to Fig. 21, collar 214 is slidably mounted on sheath 104. Before the device is inserted into the uterus, collar 214 can be positioned along sheath 104 to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head 102 has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar 214 can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

Second Exemplary Embodiment - Operation

In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar 184 (Fig. 32B) adjacent to calibration marks 182 corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section 186 to engage its internally positioned teeth with the rack 180. This locks the longitudinal position of the heel 188 (Fig. 32A) such that it will engage with the spring member 190 when the array has been exposed to the length set by the sliding collar.

Next, with the grips 142, 144 in their resting positions to keep the applicator head 102 covered by sheath 104, the distal end of the device 100 is inserted into the uterus. Once the distal end of the sheath 104 is within the uterus, grips 142, 144 are squeezed together to deploy the applicator head 102 from sheath 104. Grips 142, 144 are squeezed until heel 188 engages with locking spring member 190 as described with respect to Figs. 36A through 36C.

At this point, deflecting mechanism 102b has deployed the array 102a into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge 146. The measured length and width are entered into the RF generator system 250 (Fig. 21) and used to calculate the ablation power.

Vacuum source 252 (Fig. 21) is activated, causing application of suction to hypotube 122 via suction port 210. Suction helps to draw uterine tissue into contact with the array 102.

Ablation power is supplied to the electrode array 102a by the RF generator system 250. The tissue is heated as the RF energy passes from electrodes 118a-d to the tissue, causing moisture to be released from the tissue. The vacuum source helps to draw moisture from the uterine cavity into the hypotube 122. Moisture withdrawal is facilitated by the apertures 126 formed in flexures 124 by preventing moisture from being trapped between the flexures 124 and the lateral walls of the uterus.

If the RF generator 250 includes an impedance monitoring module, impedance may be monitored at the electrodes 118a-d and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever 194 to disengage heel 188 from locking spring member 190 and to thereby allow grips 142, 144 to move to their expanded (resting condition). Release of grips 142, 144 causes applicator head 102 to retract to its unexpanded condition and further causes applicator head 102 to be withdrawn into the sheath 104. Finally, the distal end of the device 100 is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

PATENT APPLICATION
Expr ss Mailing Label: EM503277278US

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We Claim:

1. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue.

2. The method of claim 1 wherein the fluid permeable elastic member includes metallized fabric.

3. The method of claim 1 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

4. The method of claim 3 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

5. The method of claim 4 wherein each flexure includes at least one opening and wherein step (d) includes allowing at least a portion of the moisture to pass through the openings in the flexures.

6. The method of claim 1 wherein step (d) includes permitting at least a portion of the moisture to pass from the array into the tubular member.

7. The method of claim 3 wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

8. The method of claim 1 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

9. The method of claim 1 wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

10. The method of claim 9 wherein the array is carried by a pair of elongate flexures and wherein the step of measuring the

approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

11. The method of claim 9 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

12. The method of claim 2 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

13. The method of claim 12 wherein the metallized fabric includes yarns of spandex and nylon.

14. The method of claim 2 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

15. The method of claim 1 including the step of applying suction through the tubular member to draw the tissue into contact with the electrode array.

16. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an electrode array carried by an elongate member, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.

17. The ablation and/or coagulation apparatus of claim 16 further including an elongate tube having at least one opening adjacent to the array and a vacuum source fluidly coupled to the elongate tube.

18. The apparatus of claim 16 wherein the fluid permeable elastic member includes metallized fabric.

19. The apparatus of claim 18 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

20. The apparatus of claim 18 wherein the metallized fabric includes yarns of spandex and nylon.

21. The apparatus of claim 16 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

22. The apparatus of claim 16 wherein the electrode array is carried by a deflecting mechanism moveable between a retracted position and an expanded position.

23. The apparatus of claim 22 wherein the deflecting mechanism includes a pair of elongate flexures.

24. The apparatus of claim 23 wherein the flexures include at least one fluid opening.

25. The apparatus of claim 22 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

26. The apparatus of claim 23 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

27. The apparatus of claim 16 further comprising:

width measurement means for measuring the approximate width of the organ.

28. The apparatus of claim 27 further comprising:

length measurement means for measuring the approximate length of the organ.

29. The apparatus of claim 27 further comprising means for determining an ablation power using the measured approximate width.

30. The apparatus of claim 28 further comprising means for determining an ablation power using the measured approximate width and length.

31. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an elongate member;

a deployment mechanism carried by the elongate member, the deployment mechanism moveable between a retracted position and a plurality of laterally expanded positions;

an electrode array carried by the deployment mechanism;

a sheath slidably disposed over the electrode array;

a handle coupled to the sheath and deployment mechanism, the handle moveable between an insertion position in which the sheath is disposed over the electrode array and the array is in an unexpanded condition, and a deployment position in which the electrode array extends from the distal end of the sheath and is in one of its expanded positions;

limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath; and

a source of radio frequency energy electrically coupled to the array.

PATENT APPLICATION

Express Mailing Lab I: EM503277278US

ABSTRACT OF THE DISCLOSURE

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. The array includes conductive regions separated by insulated regions arranged to produce ablation to a predetermined depth. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

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Applicant or Patentee: Csaba Tr[redacted]et al.
Appln. or Patent No.: NEW
Filed or Issued: HEREWITH
For: A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Attorney's
Docket No.: ENVS-220

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am
[] the owner of the small business concern identified below:
[X] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Novacept
ADDRESS OF CONCERN 1047 Elwell Court, Palo Alto, CA 94303

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION by inventor(s) Csaba Truckai et al. described in

[X] the specification filed herewith with title as listed above.
[] application no. , filed .
[] patent no. , issued .

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME _____
ADDRESS _____
[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

NAME _____
ADDRESS _____
[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time or paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Csaba Truckai
TITLE OF PERSON OTHER THAN OWNER Vice Pres. of Research and Development
ADDRESS OF PERSON SIGNING 1047 Elwell Court, Palo Alto, CA 94303

SIGNATURE: _____ DATE: _____

Atty Docket No. ENVS-220 []

DECLARATION FOR CIP PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship ar as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

the specification of which (check one) _X_ is attached hereto or ___ was filed on ____ as Application No. __ and was amended on ____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed Yes	No
Number	Country	Day/Month/Year Filed		
Number	Country	Day/Month/Year Filed		

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) below.

60/084,791	May 8, 1998
Application Number	Filing Date
Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

08/632,516 [Patent No. 5,769,880]	April 12, 1996	Patented
Application Number	Filing Date	Status: Patented, Pending, Abandoned
Application Number	Filing Date	Status: Patented, Pending, Abandoned

Attorney Dock. No. ENVS-220

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are beli ved to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fin or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Csaba Truckai

Inventor's signature _____ Date

Residence 627 Alberta Avenue, Sunnyvale, CA 94087

Citizenship USA

Post Office Address 627 Alberta Avenue, Sunnyvale, CA 94087

Full name of second joint inventor, if any, Russel Mahlon Sampson

Inventor's signature _____ Date

Residence 271 Diablo Ave, Mountain View, CA 94043

Citizenship USA

Post Office Address 271 Diablo Ave, Mountain View, CA 94043

Full name of third joint inventor, if any, Stephanie Squarcia

Inventor's signature _____ Date

Residence 411 California Ave, Apt. 14, Palo Alto, CA 94306

Citizenship USA

Post Office Address 411 California Ave, Apt. 14, Palo Alto, CA 94306

Full name of fourth joint inventor, if any, Alfonzo Lawrence Ramirez

Inventor's signature _____ Date

Residence 2911 Betsy Way, San Jose, CA 95133

Citizenship USA

Post Office Address 2911 Betsy Way, San Jose, CA 95133

Full name of fifth joint inventor, if any, Estela Hilario

Inventor's signature _____ Date

Residence 887 Altos Oaks Dr., Los Altos, CA 94024

Citizenship USA

Attorney Docket No. ENVS-220 II

ASSIGNMENT

WHEREAS, WE, Csaba Truckai, Russel Mehlon Sampson, Stephanie Squarcia, Alfonzo Lawrence Ramirez and Estela Hilario hereinafter referred to as "ASSIGNORS", have invented certain new and useful improvements as described and set forth in the below-identified application for United States Letters Patent:

Title of Invention: **A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

Application (Declaration/Oath) Execution Date: July 31, 1998 and August 4, 1998

Filing Date: June 23, 1998 Application No.: 09/103,072

WHEREAS, Novacept, a corporation of the State of California, 1047 Elwell Court, Palo Alto, CA 94303 hereinafter referred to as "ASSIGNEE", is desirous of acquiring the entire right, title and interest in the said invention and application and in any Letters Patent which may be granted on the same;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN: Be it known that, for One Dollar ($1.00) and other good and valuable consideration, receipt of which is hereby acknowledged by Assignors, Assignors have sold, assigned and transferred, and by these presents do sell, assign and transfer unto the said Assignee, and Assignee's successors and assigns, all right, title and interest in and to the said invention, said application for United States Letters Patent, and any Letters Patent which may hereafter be granted on the same in the United States and all countries throughout the world including any divisions, renewals, continuations in whole or in part, substitutions, conversions, reissues, prolongations or extensions thereof, said interest to be held and enjoyed by said Assignee as fully and exclusively as it would have been held and enjoyed by said Assignors had this assignment and transfer not been made, to the full end and term of any such Letters Patent.

Assignors further agree that they will, without charge to said Assignee, but at Assignee's expense, cooperate with Assignee in the prosecution of said application and/or applications, execute, verify, acknowledge and deliver all such further papers, including applications for Letters Patent and for the reissue thereof, and instruments of assignment and transfer thereof, and will perform such other acts as Assignee lawfully may request, to obtain or maintain Letters Patent for said invention and improvement in any and all countries, and to vest title thereto in said Assignee, or Assignee's successors and assigns.

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8/5/98

Csaba Truckai

State of CA

County of SANTA CLARA

On 8/5/98 before me, ANN FOSTER,

personally appeared _____ personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

SEAL

WITNESS my hand and official seal.

Signature of Notary

Attorney Docket No. ENVS-220

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 08-05-98

Russel Mahlon Sampson

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared RUSSEL MAHLON SAMPSON personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

SEAL

Signature of Notary

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8/5/98

Stephanie Squarcia

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared Stephanie Squarcia, personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

SEAL

Signature of Notary

Attorney Docket No. ENVS-220

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8-5-98

Alfonzo Lawrence Ramirez

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared Alfonzo L. Ramirez personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

SEAL

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

Signature of Notary

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8-5-98

Estela Hilario

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

Signature of Notary

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 1997

Application or Docket Number: 09/103072

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	31 minus 20 =	* 11
INDEPENDENT CLAIMS	3 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐	RATE	FEE	OR	OTHER THAN SMALL ENTITY	RATE	FEE
BASIC FEE		395.00	OR	BASIC FEE		790.00
TOTAL CLAIMS	x$11=		OR	TOTAL CLAIMS	x$22=	242.00
INDEPENDENT CLAIMS	x41=		OR	INDEPENDENT CLAIMS	x82=	
MULTIPLE DEPENDENT CLAIM PRESENT	+135=		OR	MULTIPLE DEPENDENT CLAIM PRESENT	+270=	
	TOTAL		OR		TOTAL	1032.00

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 68	Minus	** 31	= 37
Independent	* 4	Minus	*** 3	= 1
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
Total	x$11=	333	OR	Total	x$22=	666
Independent	x41=	41	OR	Independent	x82=	82
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+135=		OR	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+270=	
	TOTAL ADDIT. FEE	374	OR		TOTAL ADDIT. FEE	748

PL 6/23/03 PL 6/23/03

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
Total	x$11=		OR	Total	x$22=	
Independent	x41=		OR	Independent	x82=	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+135=		OR	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+270=	
	TOTAL ADDIT. FEE		OR		TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
Total	x$11=		OR	Total	x$22=	
Independent	x41=		OR	Independent	x82=	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+135=		OR	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+270=	
	TOTAL ADDIT. FEE		OR		TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 8/97) *U.S. Government Printing Office: 1997 - 430-571/69194 Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

HOL-MIN_146901

CLAIMS ONLY

SERIAL NO.	FILING DATE
APPLICANT(S)	

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1						
2						
3						
4						
5			1			
6			1			
7			1			
8						
9						
10						
11						
12						
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15			1			
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34				1		
35				1		
36				1		
37				1		
38				1		
39				1		
40				1		
41				1		
42				1		
43				1		
44				1		
45				1		
46				1		
47				1		
48				1		
49				1		
50				1		
TOTAL IND.			4			
TOTAL DEP.			64			
TOTAL CLAIMS			68			

	*		*		*	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51				1		
52				1		
53				1		
54				1		
55				1		
56				1		
57				1		
58				1		
59				1		
60				1		
61				1		
62				1		
63				1		
64				1		
65				1		
66				1		
67				1		
68				1		
69				1		
70				1		
71				1		
72				1		
73				1		
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75				1		
76				1		
77				1		
78				1		
79				1		
80				1		
81				1		
82				1		
83				1		
84				1		
85				1		
86				1		
87				1		
88				1		
89				1		
90				1		
91				1		
92				1		
93				1		
94				1		
95				1		
96						
97						
98						
99						
100						
TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

* MAY BE USED FOR ADDITIONAL CLAIMS OR ADMENDMENTS

FORM PTO-2022 (1-98)

U.S.DEPARTMENT OF COMMERCE
Patent and Trademark Office

*U.S. GPO: 1998-443-593/89152

SECTOR

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	Group Art Unit: 3736
Csaba Truckai et al.	Examiner: Unknown
Appln. No. 09/103,072	**RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION AND SUBMISSION OF SMALL ENTITY STATUS, POWER OF ATTORNEY, AND DECLARATION**
Filed: June 23, 1998	
For: **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**	2001 Ferry Building San Francisco, CA 94111 415/433-4150

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on August 13, 1998.

LIMBACH & LIMBACH L.L.P. Date: 8/13/98

By: Beryl Anne Keys

Name: Beryl Anne Keys

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Notice to File Missing Parts of Application mailed July 17, 1998 (copy enclosed), applicant submits the enclosed Declaration for Patent Application and Verified Statement Claiming Small Entity Status-Small Business Concern.

Also enclosed is a Power of Attorney by Assignee.

A check in the amount of $581.00 is enclosed herewith to cover the $65.00 surcharge for filing missing parts of an application, and the basic filing fee of $516.00.

The Commissioner is hereby authorized to charge payment of any **additional** fees associated with this communication or credit any overpayment to Deposit Account No. 12-1420. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

LIMBACH & LIMBACH L.L.P.

08/20/1998 SCARMICH 00000076 09103072

01 FC:201 395.00 OP
02 FC:205 65.00 OP
03 FC:203 21.00 OP

August 13, 1998
(Date)

By: Kathleen A. Frost
Kathleen A. Frost
Registration No. 37,326

ENVS-220

Attorneys for Applicant(s)

PATENTS\MISSPART.MRG

Rev. 03/06/98

HOL-MIN_146903

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/103,072	06/23/1998	TRUCKAI	ENVS-220

AUG 17 1998

0242/0717

KATHLEEN A FROST
LIMBACH & LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

NOT ASSIGNED

DATE MAILED: 3736

NOTICE TO FILE MISSING PARTS OF APPLICATION

07/17/98

Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to av id abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 1162.

☑ 1. The statutory basic filing fee is:
- ☑ missing.
- ☐ insufficient.

Applicant must submit $ 790 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $ 372 including any multiple dependent claim fees, are required.

$ _____ for _____ independent claims over 3.

$ 242 for 11 dependent claims over 20.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☑ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.

A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules.

See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

☐ 9. OTHER

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notic MUST b returned with the reply.

K. Carol Smith

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

HOL-MIN_146904

Applicant or Patentee: Csaba [redacted] et al.

Attorney's

Appln. No.: 09/103,072

Docket No.: ENVS-220

Filed: June 23, 1998

For: A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

[ ] the owner of the small business concern identified below:

[X] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Novacept

ADDRESS OF CONCERN 1047 Elwell Court, Palo Alto, CA 94303

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled **A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION** by inventor(s) Csaba Truckai et al. described in

[X] the specification filed herewith with title as listed above.

[ ] application no. , filed .

[ ] patent no. , issued .

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME _____

ADDRESS _____

[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

NAME _____

ADDRESS _____

[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time or paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Csaba Truckai

TITLE OF PERSON OTHER THAN OWNER Vice Pres. of Research and Development

ADDRESS OF PERSON SIGNING 1047 Elwell Court, Palo Alto, CA 94303

SIGNATURE: _____ DATE: 08-05-98

Atty Dock t No. ENVS-220 []

DECLARATION FOR CIP PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship ar as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

the specification of which (check one) ___ is attached hereto or __X__ was filed on June 23, 1998 as Application No. 09/103,072 and was amended on ___ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed Yes	No
Number	Country	Day/Month/Year Filed		
Number	Country	Day/Month/Year Filed		

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) below.

60/084,791	May 8, 1998
Application Number	Filing Date
Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

08/632,516 [Patent No. 5,769,880]	April 12, 1996	Patented
Application Number	Filing Date	Status: Patented, Pending, Abandoned
Application Number	Filing Date	Status: Patented, Pending, Abandoned

Attorney Dock. No. ENVS-220

I hereby d clare that all statements made h rein of my own knowledg are true and that all statements made on information and beli f are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so mad are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Csaba Truckai

Inventor's signature _____ 07.31.98 Date

Residence 627 Alberta Avenue, Sunnyvale, CA 94087

Citizenship USA

Post Office Address 627 Alberta Avenue, Sunnyvale, CA 94087

Full name of second joint inventor, if any, Russel Mahlon Sampson

Inventor's signature _____ 07.31.98 Date

Residence 271 Diablo Ave, Mountain View, CA 94043

Citizenship USA

Post Office Address 271 Diablo Ave, Mountain View, CA 94043

Full name of third joint inventor, if any, Stephanie Squarcia

Inventor's signature _____ 8/4/98 Date

Residence 411 California Ave, Apt. 14, Palo Alto, CA 94306

Citizenship USA SJS 8/4/98

Post Office Address 411 California Ave, Apt. 14, Palo Alto, CA 94306

SJS 8/4/98

Full name of fourth joint inventor, if any, ~~Alfonzo~~ Alfonso Lawrence Ramirez

Inventor's signature _____ 8-4-98 Date

Residence 2911 Betsy Way, San Jose, CA 95133

Citizenship USA

Post Office Address 2911 Betsy Way, San Jose, CA 95133

Full name of fifth joint inventor, if any, Estela Hilario

Inventor's signature _____ 8-4-98 Date

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Citizenship USA

Post Office Address 887 Altos Oaks Dr., Los Altos, CA 94024

Attorney Docket No. ENVS-220

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES PATENT

In re Patent Application of	Group Art Unit: Unknown
Csaba Truckai et al.	**POWER OF ATTORNEY BY ASSIGNEE AND CERTIFICATE BY ASSIGNEE UNDER 37 CFR § 3.73(b)**
Appln. No. 09/103,072	
Filed: June 23, 1998	
For: **A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Novacept, assignee of the entire right title and interest in the above-identified application by assignment dated 8/5/98, which assignment is [ ] recorded in the Patent and Trademark Office at Reel , frame , [X] attached hereto, hereby appoints the members of the firm of LIMBACH & LIMBACH L.L.P., a firm composed of:

Karl A. Limbach	18,689	W. Patrick Bengtsson	32,456	Kyla L. Harriel	P-41,816
George C. Limbach	19,305	Mark A. Dalla Valle	34,147	Mayumi Maeda	40,075
John K. Uilkema	20,282	Charles P. Sammut	28,901	Kent J. Tobin	39,496
Neil A. Smith	25,441	Mark C. Pickering	36,239	Christine S. Ring	P-42,106
Veronica C. Devitt	29,375	Kathleen A. Frost	37,326	Michael R. Ward	38,651
Ronald L. Yin	27,607	Alan S. Hodes	38,185	Steven M. Santisi	40,157
Gerald T. Sekimura	30,103	Patricia Coleman James	37,155	Charles L. Hamilton	P-42,624
Michael A. Stallman	29,444	Alan A. Limbach	39,749	Andrew V. Smith	P-43,132
Philip A. Girard	28,848	Douglas C. Limbach	35,249	Heath W. Hoglund	41,076
Michael J. Pollock	29,098	Brian J. Keating	39,520	J. Thomas McCarthy	22,420
Stephen M. Everett	30,050	Seong-Kun Oh*			
Alfred A. Equitz	30,922	Cameron A. King	P-41,897		

* Recognition under 37 CFR 10.9(b)

as its attorneys with full power of substitution to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith.

The assignee certifies that it has reviewed the assignment and to the best of the assignee's knowledge and belief, title is in the assignee.

Please direct all correspondence regarding this application to the following:

LIMBACH & LIMBACH L.L.P.
Attn: Kathleen A. Frost
2001 Ferry Building
San Francisco, CA 94111

Telephone: (415) 433-4150
Facsimile: (415) 433-8716

Dated: 8/10/98

Novacept

By: _____ 8-10-98
Name: Csaba Truckai
Title: Vice Pres. of Research and Development

PATENTS\PWR&ASN.MRG

Rev. 03/25/98

HOL-MIN_146908

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A list of the patent(s) or publication(s) is set forth on the attached Form PTO-1449 (Modified).

A copy of the items on PTO-1449 (Modified) is supplied herewith:

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached form PTO-1449 (Modified) are not supplied because they were previously cited by or submitted to the Office in a prior application no. , filed and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

A concise explanation of relevance of the items listed on form PTO-1449 (Modified) is:

(k) [x] not given

(l) [] given for each listed item

(m) [] given for only non-English language listed item(s) [Required]

(n) [] is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references [copy attached].

The Examiner is reminded that a "concise explanation of the relevance" of the submitted items "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention," MPEP § 609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein

is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR § 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR § 1.98 and MPEP § 609 and the Examiner is respectfully requested to consider the listed references.

[x] The Commissioner is hereby authorized to charge our Deposit Account No. 12-1420 for any fees required in connection with the filing of this Information Disclosure Statement. **A duplicate copy of this Notice is enclosed for this purpose.** In particular, in the event that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is authorized to charge the above-named deposit account for any fees required pursuant to CFR §§ 1.17(p) or 1.17(i)(1).

Respectfully submitted,
LIMBACH & LIMBACH L.L.P.

Dated: 10-16-98

By: Kathleen A. Frost
Kathleen A. Frost
Reg. No. 37,326
Tel. No. 415/433-4150

Our File: ENVS-220

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/103,072	06/23/98	TRUCKAI	C ENVS-220

EXAMINER

QM31/0621

KATHLEEN A FROST
LIMBACH & LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

ART UNIT	PAPER NUMBER
3762	6

DATE MAILED: 06/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6/23/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-31 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-4, 6, 7, 8-14, 16, 18-23, 25-31 is/are rejected.
☑ Claim(s) 5-7, 15, 17, 24 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
☐ Interview Summary, PTO-413
☑ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

Drawings

1. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1, 3, 8, 16, 22, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern et al '470.

Stern et al '460 discloses the invention substantially as claimed including an expansible member constructed of open-cell, porous material which do to its structure will act to absorb moisture when this surface is not coated with a paste or gel.

4. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Edwards.

Edwards discloses an elongate member (15), a deployment mechanism (12), an electrode array (40), a sheath (14), a handle (16), a limiting means (20, 22, 23, 24) and a source of RF energy is supplied to the electrodes (column 4, line 46).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 9-14, 18-22 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al '470.

Stern et al '470 discloses the invention substantially as claimed except for the fluid permeable member including a variety of fabrics, the step of measuring the length and width of the organ being treated and width measurment means. The material used in the construction of the

permeable member would have been an obvious design choice in the absence of any new or unobvious results, the material being used being dependent upon its absorption properties and biocompatibility with the body. It would be obvious to one of ordinary skill in the art to survey the organ being treated as to its size, shape etc. as a preliminary step in the treatment proceedure. Measurment means is accomplished by comparing the dimensions of the organ to the known measurments of the treatment mechanism.

7. Claims 4, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al '470 in view of Chin (WO 95/07664).

Stern et al. '470 discloses the invention substantially as claimed except for the use of spring members to assist in the deployment of the electrode carrying member. Chin discloses spring members (50, 52) which assist in the deployment of the balloon (10) into proper configuration in the uterus during organ ablation. It would have been obvious to one of ordinary skill in the art to provide similar additional support means in the balloon structure of Stern et al. In order to assist in the proper placement of the device in the uterus for the ablation proceedure.

Allowable Subject Matter

8. Claims 5-7, 15, 17 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record does not teach openings in elements of the device for actively withdrawing moisture from the treatment site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kent Gring whose telephone number is (703) 308-2214. The examiner can normally be reached on Monday - Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Kent Gring

June 18, 1999

CORRINE McDERMOTT
PRIMARY EXAMINER

Form PTO 948 (Rev. 8-98) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 103072

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 6/23/98 are:

A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be sumitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ___ Color drawings are not acceptable until petiton is granted. Fig(s) _____
   - ___ Pencil and non black ink not permitted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84 (b)
   - ___ 1 full-tone set is required. Fig(s) _____
   - ___ Photographs not properly mounted (must use brystol board or photographic double-weight paper). Fig(s) _____
   - ___ Poor quality (half-tone). Fig(s) _____
3. TYPE OF PAPER. 37 CFR 1.84(e)
   - ___ Paper not flexible, strong, white, and durable. Fig(s) _____
   - ___ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) _____
   - ___ Mylar, velum paper is not acceptable (too thin). Fig(s) _____
4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   - ___ 21.0 cm by 29.7 cm (DIN size A4)
   - ___ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - ___ All drawing sheets not the same size. Sheet(s) _____
   - ___ Drawings sheets not an acceptable size. Fig(s) _____
5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

   Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size

   Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11

   Margins not acceptable. Fig(s) 21 26 32 4B 36A, 37B
   - ☒ Top (T) ☒ Left (L)
   - ___ Right (R) ☒ Bottom (B)
6. VIEWS. 37 CFR 1.84(h)

   REMINDER: Specification may require revision to correspond to drawing changes.

   Partial views. 37 CFR 1.84(h)(2)
   - ___ Brackets needed to show figure as one entity. Fig(s) _____
   - ___ Views not labeled separately or properly. Fig(s) _____
   - ☒ Enlarged view not labeled separetely or properly. Fig(s) 27
7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)
   - ___ Hatching not indicated for sectional portions of an object. Fig(s) _____
   - ___ Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____
9. SCALE. 37 CFR 1.84(k)
   - ___ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(i)
    - ☒ Lines, numbers & letters not uniformly thick and well defined,clean, durable, and black (poor line quality). Fig(s) 21-36
11. SHADING. 37 CFR 1.84(m)
    - ___ Solid black areas pale. Fig(s) _____
    - ___ Solid black shading not permitted. Fig(s) _____
    - ___ Shade lines, pale, rough and blurred. Fig(s) _____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
    - ___ Numbers and reference characters not plain and legible. Fig(s) _____
    - ___ Figure legends are poor. Fig(s) _____
    - ___ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) Fig(s) _____
    - ___ English alphabet not used. 37 CFR 1.84(p)(2) Figs _____
    - ___ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____
13. LEAD LINES. 37 CFR 1.84(q)
    - ___ Lead lines cross each other. Fig(s) _____
    - ___ Lead lines missing. Fig(s) _____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
    - ___ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____
15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
    - ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____
16. CORRECTIONS. 37 CFR 1.84(w)
    - ___ Corrections not made from prior PTO-948 dated _____
17. DESIGN DRAWINGS. 37 CFR 1.152
    - ___ Surface shading shown not appropriate. Fig(s) _____
    - ___ Solid black shading not used for color contrast. Fig(s) _____

COMMENTS

REVIEWER _____ DATE 8/24/01 TELEPHONE NO. _____

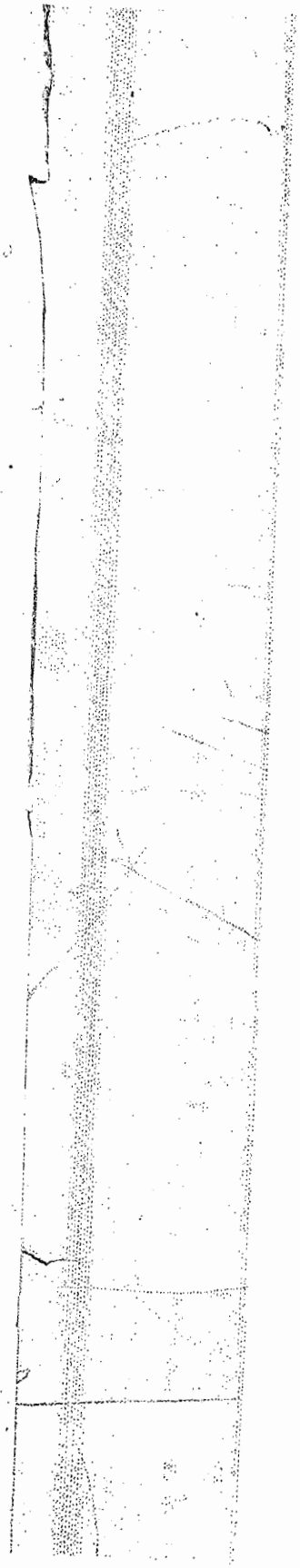
ATTACHMENT TO PAPER NO. _____

Attachment 6

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.

Substitute PTO-948



HOL-MIN_146919

PATENT

Sheet 1 of 2

FORM PTO-1449 (Modified) (Rev. 7-80)	U.S Dept. of Commerce Patent and Trademark Office	Atty Docket No. ENVS-220	Serial No. 09/103,072
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Applicant(s) Csaba Truckai ET AL.	
		Filing Date 06/23/98	Group 3736

OIPE OCT 26 1998 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	AA	1,620,929	03/15/27	Wallerich	—	—	02/05/25
	AB	1,827,306	10/13/31	Chapman et al.	—	—	09/14/25
	AC	2,190,383	02/13/40	Newman	128	401	08/29/36
	AD	2,466,042	04/05/49	Reich et al.	128	401	08/26/47
	AE	3,645,265	02/29/72	Majzlin	128	303.13	06/25/69
	AF	3,840,016	10/08/74	Lindemann	128	303.17	03/07/73
	AG	3,924,628	12/09/75	Droegemueller et al.	128	303.1	12/01/72
	AH	3,948,270	04/06/76	Hasson	128	348	10/15/74
	AI	4,057,063	11/08/77	Gieles et al.	128	303.17	02/27/76
	AJ	4,601,698	07/22/86	Moulding, Jr.	604	55	09/17/84
	AK	4,960,133	10/02/90	Hewson	128	784	11/21/88
	AL	4,662,383	05/05/87	Sogawa et al.	128	784	09/23/83
	AM	4,676,258	06/30/87	Inokuchi et al.	128	804	06/05/86
	AN	4,832,048	05/23/89	Cohen	128	786	10/29/87
	AO	4,865,047	09/12/89	Chou et al.	128	784	06/30/88
	AP	4,949,718	08/21/90	Neuwirth et al.	128	401	09/09/88
	AQ	4,961,435	10/09/90	Kitagawa et al.	128	788	10/17/88
	AR	4,979,948	12/25/90	Geddes et al.	606	33	04/13/89
	AS	5,057,106	10/15/91	Kasevich et al.	606	33	07/09/90
	AT	5,084,044	01/28/92	Quint	606	27	07/14/89
	AU	5,105,808	04/21/92	Neuwirth et al.	128	401	08/09/90
	AV	5,147,353	09/15/92	Everett	606	15	03/23/90
	AW	5,159,925	11/03/92	Neuwirth et al.	128	401	01/28/91
	AX	5,186,181	02/16/93	Franconi et al.	128	804	07/27/90
	AY	5,188,122	02/23/93	Phipps et al.	128	788	06/20/90
	AZ	5,188,602	02/23/93	Nichols	604	113	06/08/92
	BA	5,248,312	09/28/93	Langberg	606	28	06/01/92

Examiner	Date Considered
Greg Lee	6/15/99 8/24/01

* Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT

Sheet 2 of 2

FORM PTO-1449 (Modified) (Rev. 7-80)	U.S Dept. of Commerce Patent and Trademark Office	Atty Docket No. ENVS-220	Serial No. 09/103,072
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Applicant(s) Csaba Truckai ET AL.	
		Filing Date 06/23/98	Group 3736

OIPE OCT 26 1998 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	BB	5,277,201	01/11/94	Stern	607	98	05/01/92
	BC	5,308,327	05/03/94	Heaven et al.	604	96	11/25/91
	BD	5,334,193	08/02/94	Nardella	606	41	11/13/92
	BE	5,433,708	07/18/95	Nichols et al.	604	113	06/07/93
	BF	5,437,629	08/01/95	Goldrath	604	21	04/14/94
	BG	5,443,470	08/22/95	Stern et al.	607	98	04/14/93
	BH	5,364,393	11/15/94	Auth et al. (abstract only)	606	34	12/30/93
	BI	5,505,730	04/09/96	Edwards	606	41	06/24/94 -
	BJ	5,797,903	08/25/98	Swanson et al.	606	34	04/12/96
	BK	4,691,703	09/08/87	Auth et al. (abstract only)	606	31	04/25/86
	BL	4,582,057	04/15/86	Auth et al. (abstract only)	606	31	11/21/83
	BM	4,532,924	08/06/85	Auth et al.	606	50	04/30/82
	BN	4,492,231	01/08/85	Auth (abstract only)	606	42	09/17/82
	BO	4,449,528	05/22/84	Auth et al. (abstract only)	606	31	07/20/81

FOREIGN PATENT DOCUMENTS

*Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation YES	Translation NO
	BP	WO 92/19145	11/12/92	PCT	A61B	—	X	
	BQ	WO 94/07445	04/14/94	PCT	A61F		X	
	BR	0584930A1	03/02/94	EPO	A61B		X	
	BS	WO 95/07664	03/23/95	PCT	A61B		X	
	BT	WO 95/10326	04/20/95	PCT	A61N		X	
	BU	WO 94/10948	05/26/94	PCT	A61F		X	
	BV	WO 94/23794	10/27/94	PCT	A61N		X	
	BW	WO 95/05869	03/02/95	PCT	A61N		X	
	BX	WO 95/04385	02/09/95	PCT	H01Q		X	

Examiner	Date Considered
	8/24/01 6/15/99

* Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT

V. Douglas #8/a 1-4-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3736

Examiner: Gring, N

RESPONSE TO OFFICIAL ACTION MAILED JUNE 21, 1999

2001 Ferry Building
San Francisco, CA 94111
(415) 433-4150

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: , Assistant Commissioner for Patents, Washington, DC 20231, on December 21, 1999.

LIMBACH & LIMBACH LLP Date: 12/21/99

By: Pat Gamble
Pat Gamble

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicants make the following amendments and remarks in response to the official action mailed June 21, 1999:

In the Claims:

Please amend Claims 5-7, 15, 17 and 24:

5. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 4 wherein each flexure includes]

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the

Rev. 09/15/99

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2001 Ferry Building
San Francisco, CA 94111
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Attorney Docket No. ENVS-220

In re Patent Application of: Csaba Truckai et al.

Application No.: 09/103,072

Filed: June 23, 1998

For: **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated as shown below.

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL	* 33	MINUS	** 31	= 2	x 18 =	$ 36
INDEP.	* 11	MINUS	*** 3	= 8	x 78 =	$ 624
FIRST PRESENTATION OF MULTIPLE DEP CLAIM					+260 =	
					TOTAL	$ 670.00
Small Entity 50% Filing Fee Reduction (if applicable)						$ 335.00

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
The "Highest Number Previously Paid For" (Total or Independent is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.)

1. ___ No additional fee is required.

2. _X_ A check in the amount of $770.00 is attached to cover additional claims fee and three month extension of time.

3. _x_ Please charge any additional fees, including any fees necessary for extensions of time, or credit overpayment to Deposit Account No. 12-1420.
A duplicate copy of this sheet is enclosed.

4. _x_ Petition for extension of time. The undersigned attorney of record hereby petitions for an extension of time pursuant to 37 C.F.R. § 1.136(a), as may be required, to file this response.

LIMBACH & LIMBACH L.L.P.

Dated: December 21, 1999 By: _____
Kathleen A. Frost
Registration No. 37,326
Attorneys for Applicant(s)

CERTIFICATE OF MAILING

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Dated: December 21, 1999 By: _____

electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

6. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 1 wherein step (d) includes]

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from tissue and

permitting at least a portion of the moisture to pass from the array into the tubular member.

7. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 3 wherein step (d) includes the step of]

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue, including applying suction to draw the moisture through the tubular member.

15. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 1 including the step of]

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid

permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

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17. (AMENDED) An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

[The ablation and/or coagulation apparatus of claim 16 further including an elongate tube having at least one opening adjacent to the array and a vacuum source fluidly coupled to the elongate tube]

an electrode array carried by an elongate member, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array;

an elongate tube having at least one opening adjacent to the array;

and a vacuum source fluidly coupled to the elongate tube.

24. (AMENDED) An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

[The apparatus of claim 23 wherein the flexures include at least one fluid opening]

an electrode array carried by a deflecting mechanism moveable between a retracted position and an expanded position wherein the deflecting mechanism includes a pair of elongate flexures that include at least one fluid opening, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.

Please add new Claims 32 and 33:

--32. (NEW) A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate member, the electrode array including a fluid permeable metallized fabric member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue.

--33. (NEW) An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an electrode array carried by an elongate member, the array including a fluid permeable metallized fabric member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.--

REMARKS

Claims 5-7, 15, 17, and 24 have been amended. New Claims 32 and 33 are added. Claims 1 – 33 are now pending.

I. Prior Art Rejections

A. *Rejections Under U.S.C. §102*

Claims 1, 3, 8, 16, 22, 25 and 26 have been rejected under 35 U.S.C. §102 as being anticipated by Stern et al, U.S. Patent 5,433,470.

Applicants respectfully submit that the Stern reference fails to disclose or fairly suggest the step of permitting moisture generated during the dehydration of tissue to pass into an electrode carrying member and away from the tissue, as recited in Claims 1, 3 and 8. The

open-cell, porous material mentioned at Stern Col. 5, lines 47-53 is described as being filled with gel or foam, which is critical to the Stern device's ability to deliver energy to the underlying tissue. The reference appears to include no mention or suggestion for permitting, either actively or passively, moisture to pass into the material and away from the tissue.

Likewise, there is no disclosure in Stern of a fluid permeable elastic member configured to permit moisture generated during ablation to pass into the electrode carrying member and away from underlying tissue, as is recited in Claims 16, 22, 25 and 26. For this reason, Claims 1, 3, 8, 16, 22, 25 and 26 are not anticipated by Stern.

Claim 31 stands rejected as being anticipated by Edwards. However, as far as Applicants can see Edwards lacks teaching of "limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath." Edwards' switch 20 rotates the viewing optics. Switch 21 controls movement of sleeve 14. Switch 22 causes hinge 18 to pivot the balloon 12. Switch 23 controls RF delivery. Switch 24 controls flow of electrolytic solution. As far as Applicant can see, there is no mechanism that allows longitudinal extension of Edwards' electrode from the sheath to be selectively limited so as to be, for example, commensurate with the measured length of a patient's uterus. Accordingly, Claim 31 is not anticipated by Edwards.

B. Rejections Under U.S.C. § 103

Claims 2, 9-14, 18-22 and 27-30 have been rejected as being made obvious by Stern.

As discussed, Stern fails to teach of the step of permitting moisture generated during the dehydration of tissue to pass into an electrode carrying member and away from the tissue, as is recited in Claims 2, 9-14. It also fails to teach the use of a fluid permeable elastic member configured to permit moisture generated during ablation to pass into the electrode carrying member and away from underlying tissue, as is recited in Claims 18-22 and 27-30. Moreover, Applicants can find no suggestion for modifying the Stern method/apparatus to utilize the recited steps/features. Thus Claims 2, 9-14, 18-22 and 27-30 are not made obvious by the teachings of Stern.

With respect to Claims 2, 12 - 14, 18-21, an additional basis for the patentability of the claims resides in the recitation of metallized fabric in the array. Applicants can find no fair suggestion for the utilization of a metallized fabric in the Stern device, and respectfully submit that one of skill in the art would not have considered the metallized fabric to be an obvious design choice on the Stern device.

C. Rejection based on Stern in View of Chin

Claims 4, 23 and 26 have been rejected as being made obvious by Stern in view of Chin. As discussed, Stern fails to teach of the step of permitting moisture generated during dehydration to pass into an electrode

carrying member and away from the tissue, as is recited in Claim 4, and it lacks any teaching of the use of a fluid permeable elastic member configured to permit moisture generated during ablation to pass into the electrode carrying member and away from underlying tissue, as is recited in Claims 23 and 26. These teachings are likewise missing from Chin, which discloses the use of an inflatable balloon that is filled with heated liquid and used for thermal ablation.

Thus, Claims 4, 23 and 26 are not made obvious by the combined teachings of these references.

II. Allowable Subject Matter

Applicants note with appreciation the Examiner's indication that Claims 5-7, 15, 17, and 24 would be allowable if rewritten in independent form. These claims are now independent of the rejected base claims and their allowance is respectfully requested.

III. New Claims 32 and 33

New Claims 32 and 33 recite the use of metallized fabric and thus are allowable on this basis.

IV. Conclusion

For the foregoing reasons, Applicants respectively submit that

the application is in condition for allowance. Early reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

LIMBACH & LIMBACH L.L.P.

Dated: 12-21-99 By: Kathleen A Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220 []

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trad mark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,072	06/23/98	TRUCKAI C	ENVS-220

QM32/1003

KATHLEEN A FROST
LIMBACH & LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

EXAMINER	
LAM, A	
ART UNIT	**PAPER NUMBER**
3763	12

DATE MAILED: 10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

U.S. G.P.O. 2000 ; 465-166/25266

1- File Copy

HOL-MIN_146944

Office Action Summary	Application No.	Applicant(s)	
	09/103,072	TRUCKAI ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *21 December 1999* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-7,15,17,24 and 31* is/are allowed.

6)☒ Claim(s) *1-4,8-14,16,18-23,25-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 8, 16, 22, 25, 26, 32 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern et al., 5,433,470, as described in office action dated June 18, 1999. New claims 32 and 33 are same as claims 1 and 16, respectively, and thus are rejected for the same reasons as claims 1 and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 9-14, 18-22 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al '470, as described in office action dated June 18, 1999.

Claims 4, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. '470 in view of Chin (WO 95/07664) as described in office action dated June 18, 1999.

Response to Arguments

Applicant's arguments filed December 21, 1999 have been fully considered but they are not persuasive. Stern '470 discloses the open-cell, porous material as capable of permitting fluid to pass into it, see column 5, lines 47-53. The porous material is the fluid permeable elastic member. As to Edwards, 5,505,730,

Allowable Subject Matter

Claims 5-7, 15, 17, 24 and 31 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Richard can be reached on (703)305-3009. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
September 29, 2000

Sharon Kennedy
Primary Examiner

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3763

Examiner: LAM, A

PRELIMINARY AMENDMENT RESPONSIVE TO FINAL ACTION MAILED OCTOBER 3, 2000

121 Spear Street, Suite 290
San Francisco, CA 94105
(415) 512-1312

CERTIFICATE OF EXPRESS MAIL

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee": Express Mail Label No. EL816893930US addressed to: Commissioner for Patents, Washington, DC 20231, on March 5, 2001.

STALLMAN & POLLOCK LLP Date: 3/5/01

By: Georgia K. Stith
Georgia Stith

Commissioner for Patents
Washington, DC 20231

Sir:

Applicants submit this preliminary amendment in connection with the CPA application filed herewith. The CPA application is filed to permit consideration of a supplemental Information Disclosure Statement being submitted in order to disclose new references submitted in a Request for Reexamination filed against Applicants' U.S. Patent 5,769,880 (of which the present application is a CIP). To date two such Requests have been filed against the '880 patent. Copies of the Requests are also listed on the IDS and enclosed herewith.

In the Claims

Please cancel Claims 1-4, 8-14, 16, 18-23, 25-30, 32 and 33.

Please add new Claims 34 - 108:

--34. The method of claim 5 wherein the fluid permeable elastic member includes metallized fabric.

35. The method of claim 5, wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

36. The method of claim 5 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

37. The method of claim 5 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

38. The method of claim 5 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

39. The method of claim 38 wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

40. The method of claim 39 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

41. The method of claim 34 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

42. The method of claim 41 wherein the metallized fabric includes yarns of spandex and nylon.

43. The method of claim 5 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

44. The method of claim 5 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

45. The method of claim 6 wherein the fluid permeable elastic member includes metallized fabric.

46. The method of claim 6, wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

47. The method of claim 6 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

48. The method of claim 6 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

49. The method of claim 6 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

50. The method of claim 49 wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of

measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

51. The method of claim 50 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

52. The method of claim 45 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

53. The method of claim 52 wherein the metallized fabric includes yarns of spandex and nylon.

54. The method of claim 6 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

55. The method of claim 6 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

56. The method of claim 55 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

57. The method of claim 56 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

58. The method of claim 7 wherein the fluid permeable elastic member includes metallized fabric.

59. The method of claim 7, wherein the step of applying suction further includes applying suction to draw tissue into contact with the electrode array.

60. The method of claim 7 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

61. The method of claim 7 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

62. The method of claim 7 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

63. The method of claim 62 wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

64. The method of claim 63 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

65. The method of claim 58 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

66. The method of claim 65 wherein the metallized fabric includes yarns of spandex and nylon.

67. The method of claim 7 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

68. The method of claim 7 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

69. The method of claim 68 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

70. The method of claim 69 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

71. The method of claim 15 wherein the fluid permeable elastic member includes metallized fabric.

72. The method of claim 15, wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

73. The method of claim 15 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

74. The method of claim 15 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

75. The method of claim 15 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

76. The method of claim 15 wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

77. The method of claim 15 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

78. The method of claim 71 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

79. The method of claim 78 wherein the metallized fabric includes yarns of spandex and nylon.

80. The method of claim 15 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

81. The method of claim 15 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

82. The method of claim 81 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

83. The method of claim 15 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

84. The apparatus of claim 17 wherein the fluid permeable elastic member includes metallized fabric.

85. The apparatus of claim 84 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

86. The apparatus of claim 84 wherein the metallized fabric includes yarns of spandex and nylon.

87. The apparatus of claim 17 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

88. The apparatus of claim 17 wherein the electrode array is carried by a deflecting mechanism moveable between a retracted position and an expanded position.

89. The apparatus of claim 88 wherein the deflecting mechanism includes a pair of elongate flexures.

90. The apparatus of claim 88 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

91. The apparatus of claim 89 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

92. The apparatus of claim 17 further comprising:

width measurement means for measuring the approximate width of the organ.

93. The apparatus of claim 92 further comprising:

length measurement means for measuring the approximate length of the organ.

94. The apparatus of claim 92 further comprising means for determining an ablation power using the measured approximate width.

95. The apparatus of claim 93 further comprising means for determining an ablation power using the measured approximate width and length.

96. The apparatus of claim 92, wherein the measurement means includes a pair of elongate flexures, the flexures carrying the electrode array.

97. The apparatus of claim 24 wherein the fluid permeable elastic member includes metallized fabric.

98. The apparatus of claim 97 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

99. The apparatus of claim 97 wherein the metallized fabric includes yarns of spandex and nylon.

100. The apparatus of claim 24 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

102. The apparatus of claim 24 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

103. The apparatus of claim 24 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

104. The apparatus of claim 24 further comprising:

width measurement means for measuring the approximate width of the organ.

105. The apparatus of claim 104 further comprising:

length measurement means for measuring the approximate length of the organ.

106. The apparatus of claim 104 further comprising means for determining an ablation power using the measured approximate width.

107. The apparatus of claim 105 further comprising means for determining an ablation power using the measured approximate width and length.

108. The apparatus of claim 104, wherein the width measurement means includes the elongate flexures.--

REMARKS

Claims 1-4, 8-14, 16, 18-23, 25-30, 32 and 33 are cancelled. Applicants reserve the right to resubmit these or similar claims in a continuation application.

Claims 5-7, 15, 17, 24 and 31 remain in the case. **These claims were allowed in the Final Office Action mailed October 3, 2000.**

Claims 34 - 108 are new. Claims 5-7, 15, 17, 24, 31 and 34 - 108 are now pending.

All of the new claims are dependent on an allowed claim. Specifically:

Claims 34 - 44 are dependent on Claim 5.

Claims 45 - 57 are dependent on Claim 6.

Claims 58 - 70 are dependent on Claim 7.

Claims 71 - 83 are dependent on Claim 15.

Claims 84 - 96 are dependent on Claim 17.

Claims 97 - 108 are dependent on Claim 24.

Support for the subject matter in each of the new claims is found in the original claims and disclosure.

Given that all new claims are dependent on an allowed claim, allowance of all claims is requested.

Respectfully submitted,

STALLMAN & POLLOCK L.L.P.

Dated: 3-5-2001 By: Kathleen A Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,072	06/23/98	TRUCKAI	C ENVS-220

QM12/0522

KATHLEEN A. FROST
STALLMAN & POLLOCK LLP
121 SPEAR STREET
SUITE 290
SAN FRANCISCO CA 94105

EXAMINER	
LAM, A	
ART UNIT	PAPER NUMBER
3763	14

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

HOL-MIN_146971

Offic Action Summary	Application N . 09/103,072	Applicant(s) TRUCKAI ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,15,17,24,31 and 34-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *5-7, 15, 17, 24, 31 and 34-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5-7, 15, 84-108, drawn to a method of ablating and/or coagulating tissue, classified in class 604, subclass 509.

II. Claims 31, 34-83, 17 and 24, drawn to an apparatus for ablating and/or coagulating, classified in class 607, subclass 101.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, such as using the product to determine the length and width of an organ for medical treatment purposes other than to select an ablation power which is proportional to the measured length times the measured width.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
May 20, 2001

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
5/24/01

3763

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

6-12-01

In re Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3763

Examiner: LAM, A

RESPONSE TO RESTRICTION REQUIREMENT MAILED MAY 22, 2001

121 Spear Street, Suite 290
San Francisco, CA 94105
(415) 512-1312

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope, addressed to: Commissioner for Patents, Washington, DC 20231 on June 5, 2001.

STALLMAN & POLLOCK LLP

Dated: 6/5/01 By: Chanti Appling

Commissioner for Patents
Washington, DC 20231

Sir:

Applicants request that the Patent and Trademark Office withdraw the Restriction Requirement mailed May 22, 2001.

This application is a CPA application filed to permit consideration of a supplemental Information Disclosure Statement. Before the CPA was filed, Claims 5-7, 15, 17, 24 and 31 were **allowed in the Final Office Action mailed October 3, 2000.** These claims have been pending for nearly three years - since the application was filed in June 1998 - and were addressed in a substantive office action in June 1999 before they were indicated allowable in October 2000. Thus, search and examination of both method and apparatus claims has already been conducted by the Examiner. For this reason, it would not unduly burden the PTO to have these claims remain pending in the case.

The addition of new Claims 34-108 does not present additional burden, in that **ach of th new claims is d pend nt on a claim that has b n allow d.** Specifically:

Claims 34 - 44 are dependent on Claim 5.
Claims 45 - 57 are dependent on Claim 6.
Claims 58 - 70 are dependent on Claim 7.
Claims 71 - 83 are dependent on Claim 15.
Claims 84 - 96 are dependent on Claim 17.
Claims 97 - 108 are dependent on Claim 24.

Given that Claims 5-7, 15, 17, 24 and 31 have been allowed, and further given that each of Claims 34-108 is dependent on an allowed claim, Applicant respectfully requests withdrawal of the Restriction Requirement.

In the event the Restriction Requirement is not withdrawn, Applicant provisionally elects the method claims, Claims 5-7, 15, 84-108, with traverse.

Respectfully submitted,

STALLMAN & POLLOCK L.L.P.

Dated: 6-5-01 By: Kathleen A. Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,072	06/23/98	TRUCKAI C	ENVS-220

EXAMINER

QM32/0829

LAM, A

KATHLEEN A. FROST
STALLMAN & POLLOCK LLP
121 SPEAR STREET
SUITE 290
SAN FRANCISCO CA 94105

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Offic Action Summary	Application N .	Applicant(s)	
	09/103,072	TRUCKAI ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication app ars on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,15,17,24, 31 and 34-108* is/are pending in the application.

4a) Of the above claim(s) *1-4,8-14,16,18-23,25-30,32 and 33* is/are withdrawn from consideration.

5)☒ Claim(s) *5-7,15 and 34-83* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5-7,15,17,24,31 and 34-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the method claims, in Paper No. 18 is acknowledged. The traversal is on the ground(s) that search and examination of both method and apparatus claims has already been conducted by the Examiner before the CPA was filed, and that the new claims are dependent on a claim that has been previously allowed. Thus Applicant alleges that it would not unduly burden the PTO to have these claims remain pending in the present case. This is not found persuasive because a CPA requires further search and consideration of all the claims, even if they have been previously searched, considered and allowed. Moreover, the method claims and the apparatus claims are directed to different embodiments of Applicant's invention, and thus a search of the method claims does not require a search in all the same classes and subclasses as would be required for the apparatus claims. The requirement is still deemed proper and is therefore made FINAL.

Furthermore, Applicant elected the method claims in Paper No. 18, but indicated that the method claims are Claims 5-7, 15, and 84-108, see page 2, line 14, of Applicant's response. Examiner would like to point out that this is incorrect, and that the method claims are actually Claims 5-7, 15 and 34-83.

Allowable Subject Matter

Claims 5-7, 15 and 34-83 are allowed.

Conclusion

This application is in condition for allowance except for the following formal matters:

Claims 17, 24, 31 and 84-108, as being directed to non-elected claims with traverse in Paper number 18, must be canceled by Applicant before the method claims may be allowed.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

A.L.
August 25, 2001

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
8/27/01.

Notice of References Cited	Application/Control No. 09/103,072	Applicant(s)/Patent Under Reexamination TRUCKAI ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-6,159,207	12-2000	Yoon	606	41
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

ATTY DOCKET NO.	SERIAL NO.
ENVS-220	09/103,072
Csaba Truckai	
FILING	GROUP
June 23, 1998	3763

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A	5,797,903	8/25/98	Swanson et al.	606	34	4/12/96
	B	5,879,348	3/9/99	Owens et al.	606	41	4/12/96
	C	5,891,136	4/6/99	McGee et al.	606	41	4/8/96
	D	5,078,717	7/7/92	Parins et al.	606	48	9/10/90

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		E	D. E. Haines and A. F. Verow, Observations on Electrode-Tissue Interface Temperature and Effect on Electrical Inpendance During Radiofrequency Ablation of Ventricular Myocardium. Circulation Vol. 82, No. 3, Sept. 1990
		F	Abstracts Fron the 67th Scientific Sessions Dallas Convention Center Dallas, Texas November 14-17, 1994. Circulation Vol. 90, No. 4, Part 2, October 1994

EXAMINER	DATE CONSIDERED
	6/11/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
ENVS-220	09/103,072
Applicant(s) Csaba Truckai	
Filing Date June 23, 1998	**Group Art Unit** 3763

*EXAMINER INITIAL		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	G	W. M. Jackman et al. Radiofrequency Current Directed Across the Mitral Anulus with a Bipolar Epicardial-Endocardial Catheter Electrode Configuration in Dogs. Circulation Vol. 78, No. 5, November 1988.
	H	First Request for Reexamination of U. S. 5,769,880, Reexamination Control Number 90/005,435
	I	Second Request for Reexamination of U. S. 5,769,880, Reexamination Control Nuimber 90/005,866

EXAMINER	DATE CONSIDERED
	6/11/02

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3763

Examiner: LAM, A

RESPONSE TO OFFICE ACTION

121 Spear Street, Suite 290
San Francisco, CA 94105
(415) 512-1312

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope, addressed to: Commissioner for Patents, Washington, DC 20231 on February 28, 2002.

STALLMAN & POLLOCK LLP

Dated: 2/28/02 By: _____
Janet Chan

Commissioner for Patents
Washington, DC 20231

Sir:

Applicant makes the following amendments and remarks in response to the Official Action mailed August 29, 2001.

In the Claims

Please cancel Claims 17, 24, 31 and 84-108 without prejudice.

REMARKS

I. Cancellation of Claims 17, 24, 31 and 84-108

Claims 5-7, 15 and 34-83 were allowed in the Official Action mailed August 29, 2001. In view of the cancellation of Claims 17, 24, 31 and 84-108, only allowed claims remain in the case. Since only allowed claims remain in the case, Applicants respectfully request issuance of a Notice of Allowance.

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PATENT

II. IDS Filed March 5, 2001

Applicant requests acknowledgment of the IDS filed (with copies of all references) on March 5, 2001. A copy of that IDS is attached.

III. New IDS

A Supplemental Information Disclosure Statement is attached for the Examiner's consideration.

Respectfully submitted,

STALLMAN & POLLOCK L.L.P.

Dated: February 28, 2002 By: Kathleen A. Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220

US005443470A

United States Patent [19]

Stern et al.

[11] Patent Number: 5,443,470

[45] Date of Patent: * Aug. 22, 1995

[54] **METHOD AND APPARATUS FOR ENDOMETRIAL ABLATION**

[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**; **Robert L. Marion**, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto, Calif.

[*] Notice: The portion of the term of this patent subsequent to Jan. 11, 2011 has been disclaimed.

[21] Appl. No.: **46,683**

[22] Filed: **Apr. 14, 1993**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 877,567, May 1, 1992, Pat. No. 5,277,201.

[51] **Int. Cl.**[6] **A61N 5/00**

[52] **U.S. Cl.** **607/98**; 607/99; 607/113; 607/138; 606/32; 606/41

[58] **Field of Search** 606/27, 28, 32, 33, 606/40, 41, 45, 49; 607/98, 99, 113, 116, 138, 148

[56] **References Cited**

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1,827,306	10/1931	Chapman et al. .	
3,324,847	6/1967	Zoumboulis .	
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(List continued on next page.)

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WO87/01276	3/1987	WIPO .	

OTHER PUBLICATIONS

"Hyperthermia Overview Using Microwave Antennas", Invited Lectures, Thomas P. Ryan, M.D. Thermoradiotherapy, C. T. Coughlin, M.D.

"Devices: Replaceing the Roto-Rooter", Trends, Michael Dolan.

(List continued on next page.)

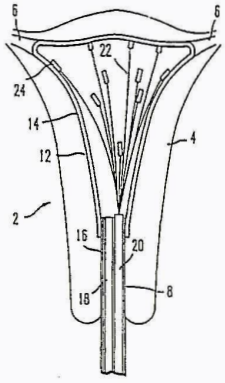
Primary Examiner—Lee S. Cohen

Attorney, Agent, or Firm—Oblon, Spivak, McClelland, Maier & Neustadt

[57] **ABSTRACT**

An endometrial ablation apparatus and method wherein an RF current having a frequency of between 250 kHz and 100 MHz is passed through the entire surface of an endometrium in order to provide heating of the endometrium. An electroconductive expandable member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The temperature of the endometrium is raised to a temperature between 45° C. and 90° C. and preferably not above 70° for a time sufficient to destroy the cells of the lining while maintaining the average temperature of the myometrium at a temperature below approximately 42° C. The expandable balloon is connected to a power source which provides the radio frequency power having the desired characteristics to selectively heat the endometrial lining to the desired temperature. The balloon can be constructed with an electroconductive elastomer such as a mixture of polymeric elastomer and electroconductive particles or can be a non-extensible bladder having a shape and a size, in its fully expanded form, which will extend the organ and effect contact with the endometrial lining to be destroyed. The electroconductive member may consist of a plurality of electrode area segments having a thermistor associated with each electrode segment whereby the temperature from each of said plurality of segments is monitored and controlled by a feedback arrangement from the thermistors.

22 Claims, 13 Drawing Sheets



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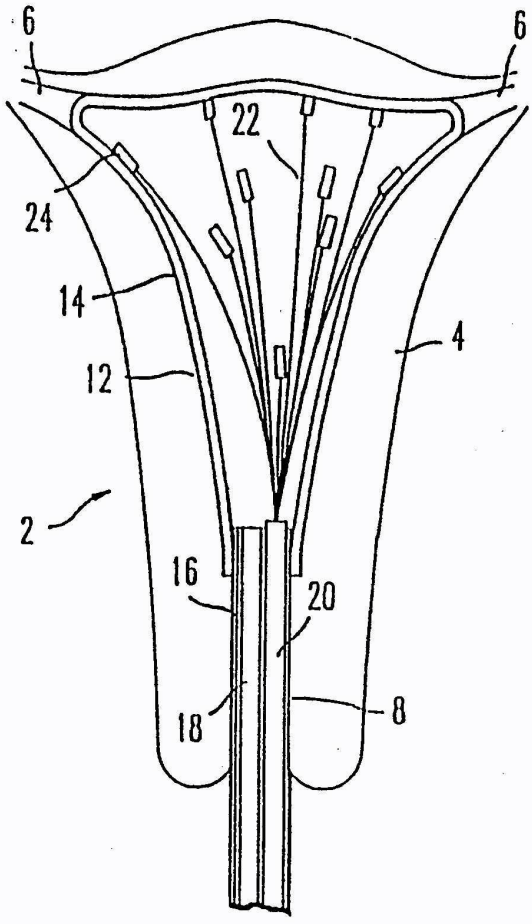


FIG. 1

FIG. 2

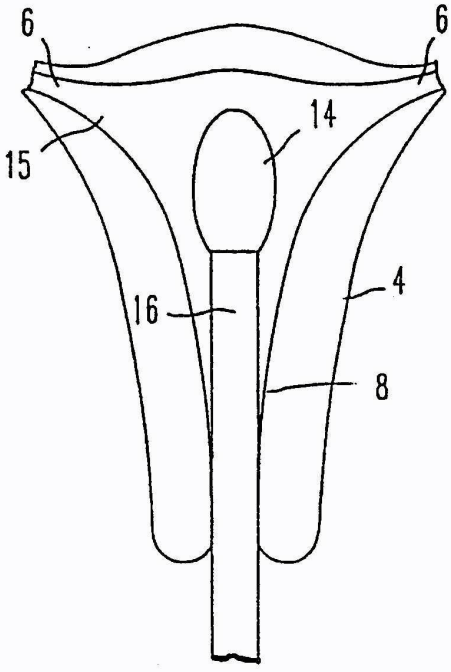
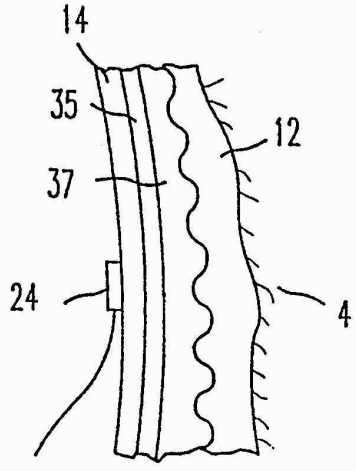


FIG. 3



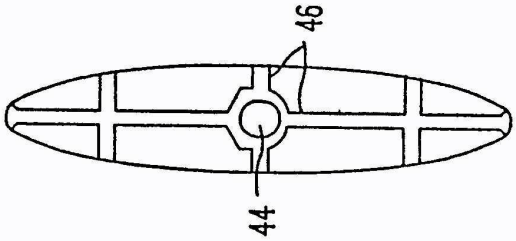


FIG. 4b

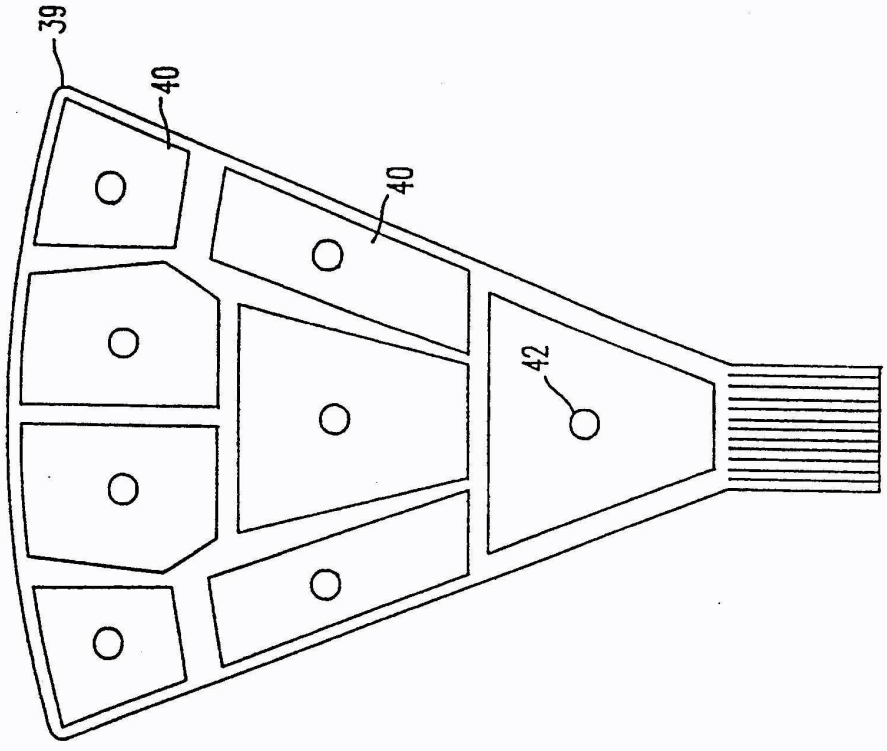
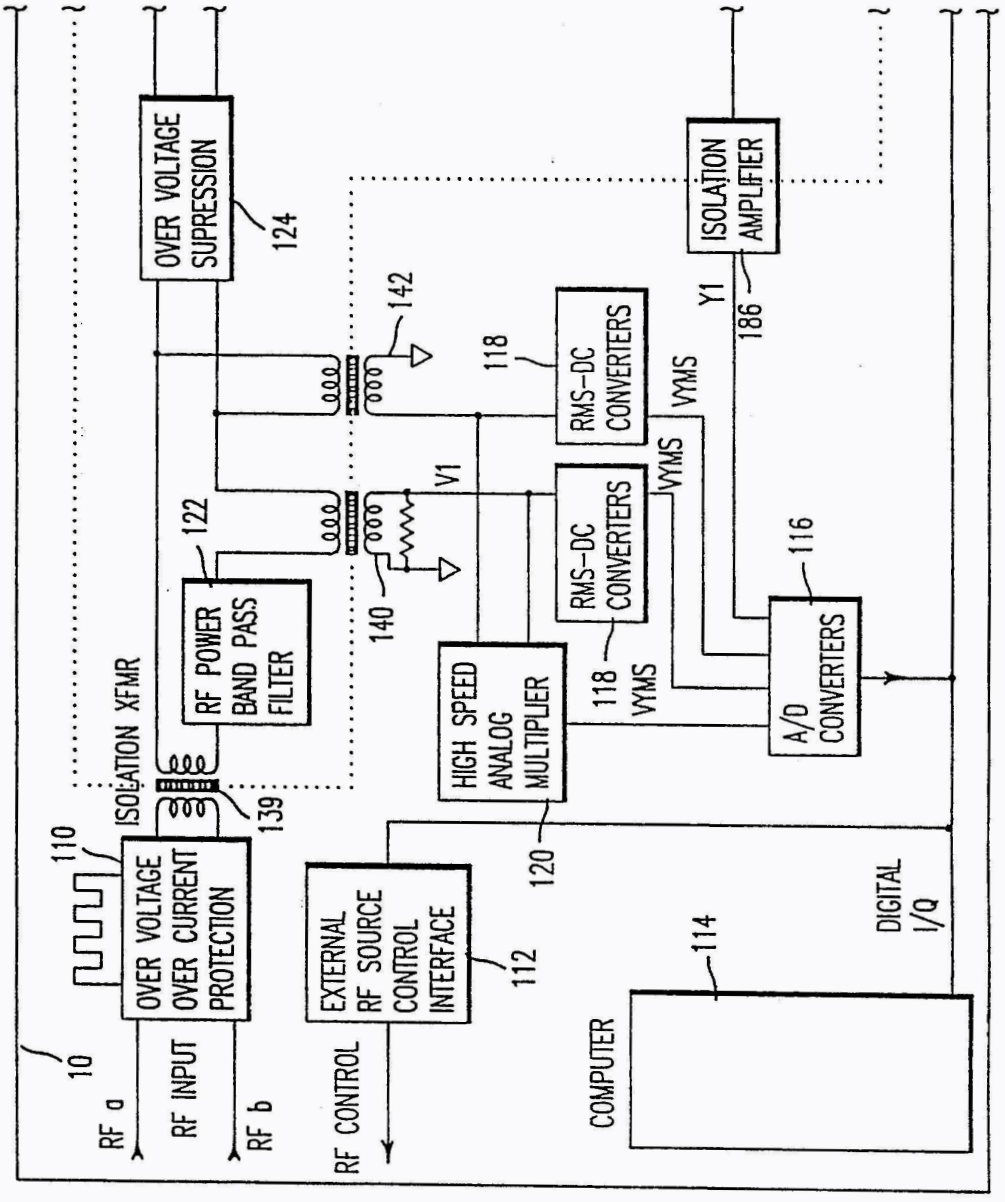


FIG. 4a

FIG. 5a


10
RF a
RF INPUT
RF b
RF CONTROL
110
OVER VOLTAGE OVER CURRENT PROTECTION
ISOLATION XFMR
139
EXTERNAL RF SOURCE CONTROL INTERFACE
112
120
HIGH SPEED ANALOG MULTIPLIER
RF POWER BAND PASS FILTER
122
140
V1
142
OVER VOLTAGE SUPRESSION
124
118
RMS-DC CONVERTERS
VYMS
118
RMS-DC CONVERTERS
VYMS
ISOLATION AMPLIFIER
Y1
186
116
A/D CONVERTERS
DIGITAL I/Q
114
COMPUTER

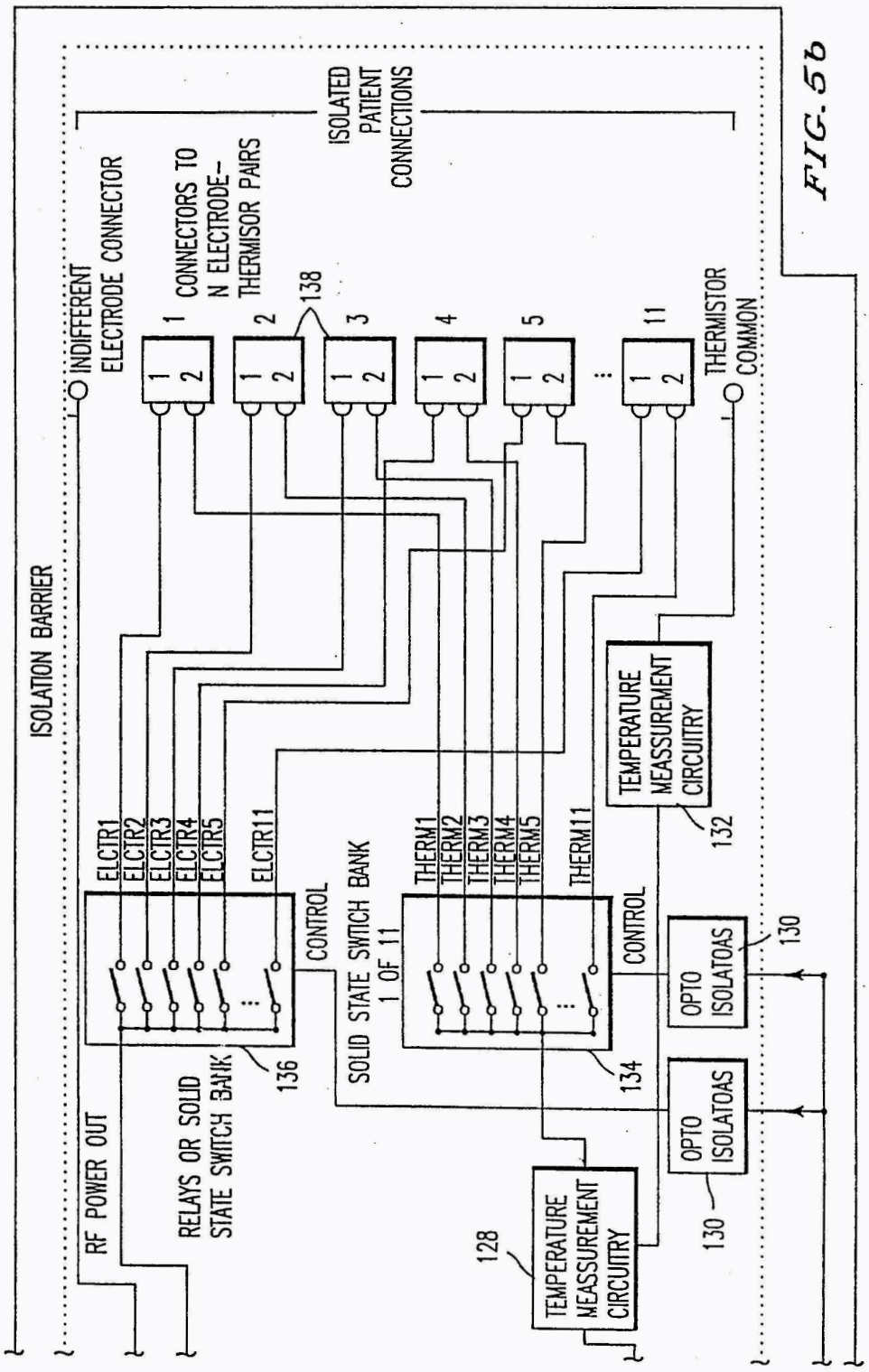


FIG. 5b

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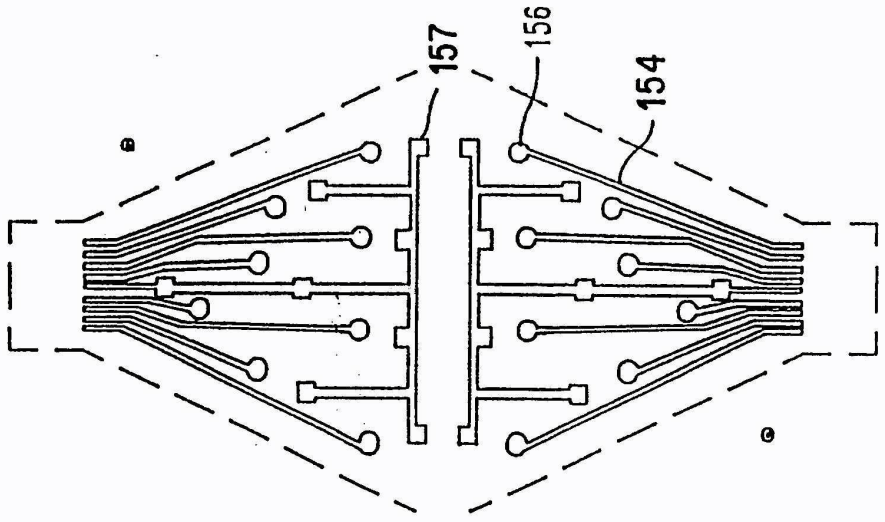


FIG. 7

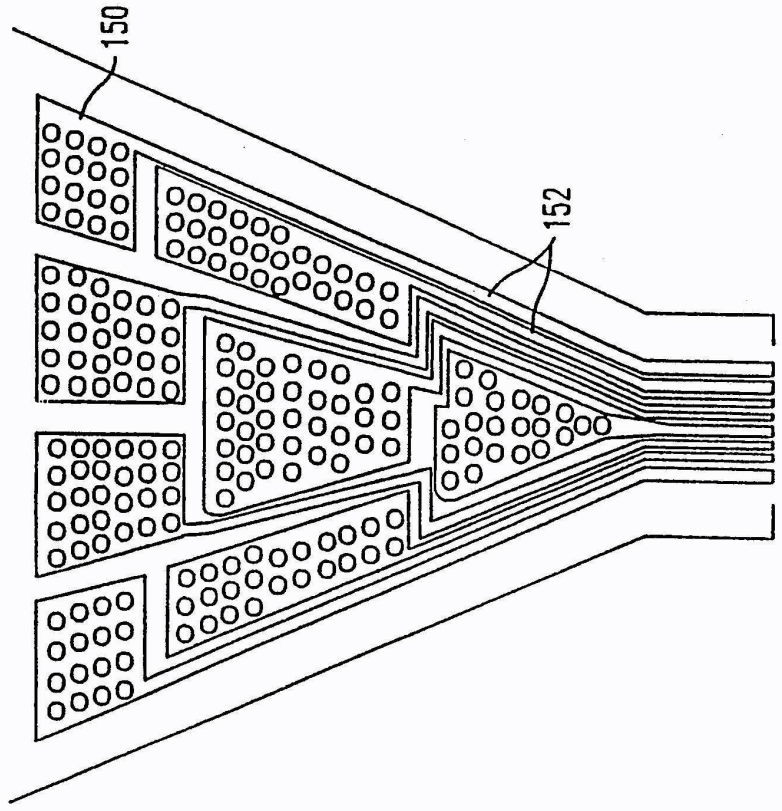


FIG. 6

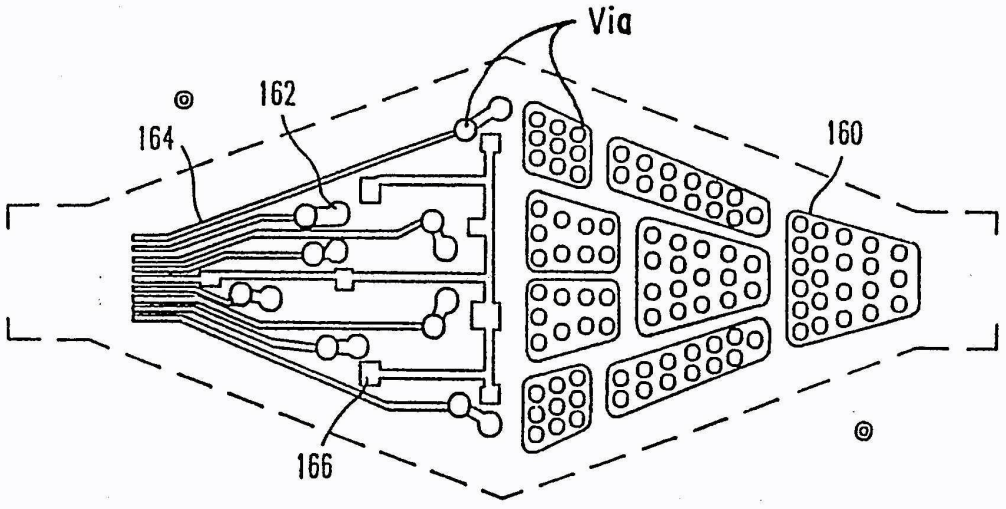


FIG. 8a

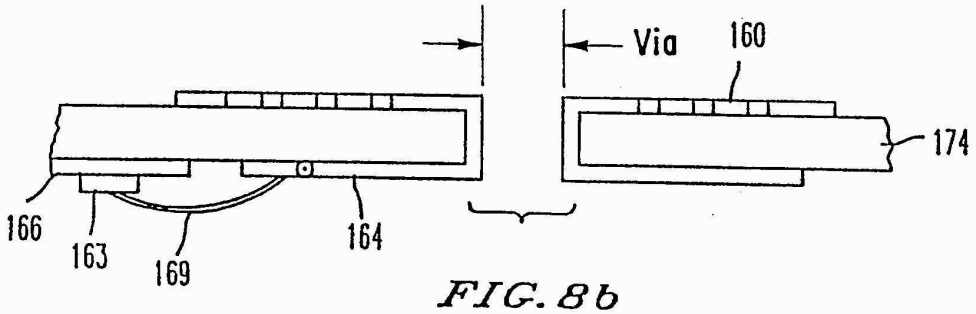


FIG. 8b

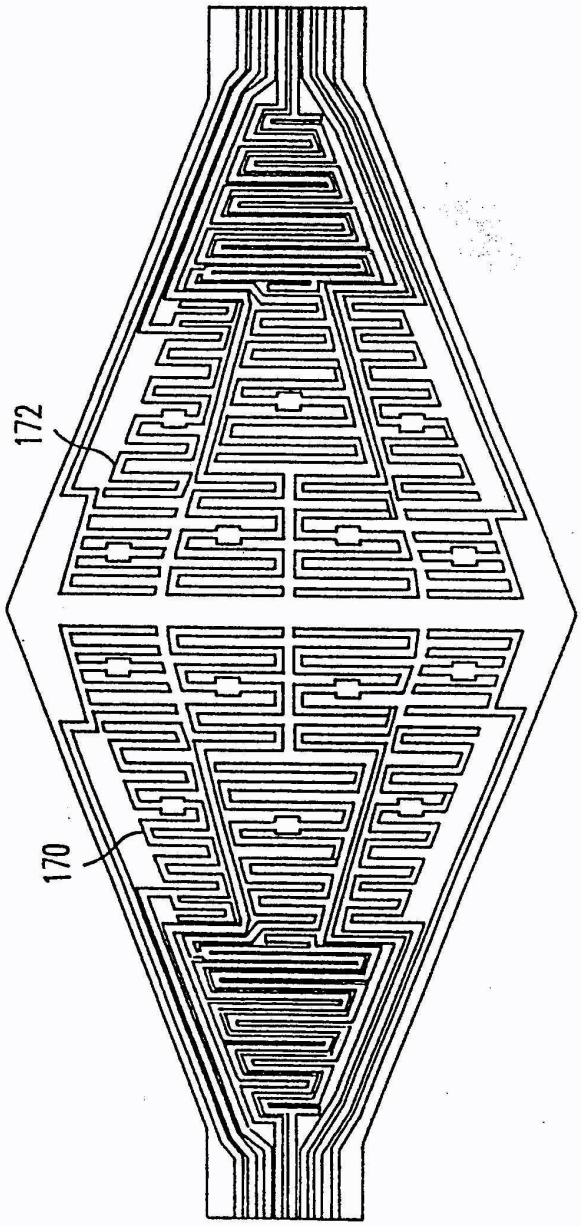


FIG. 9

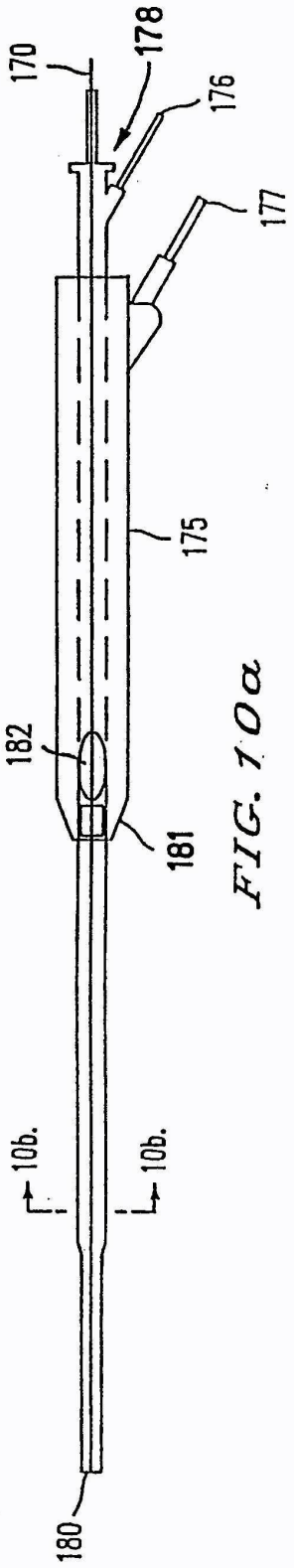


FIG. 10a

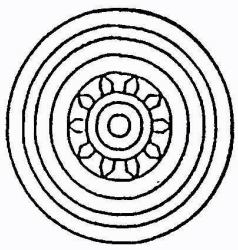


FIG. 10b

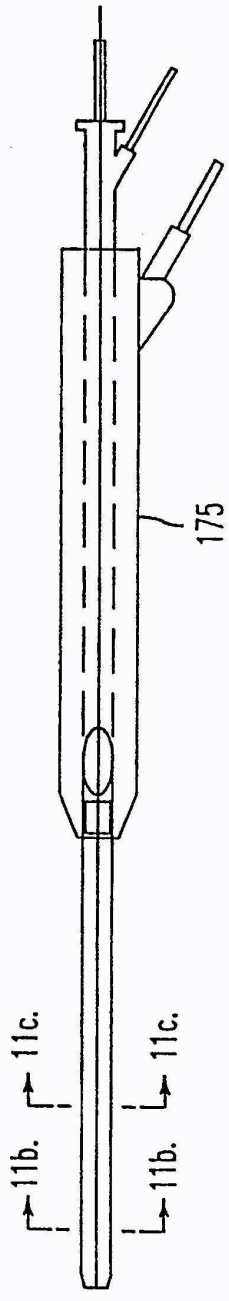


FIG. 11a

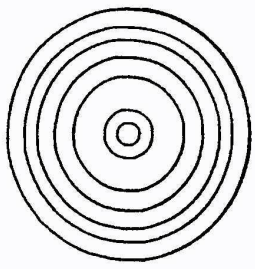


FIG. 11c

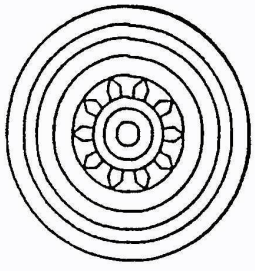


FIG. 11b

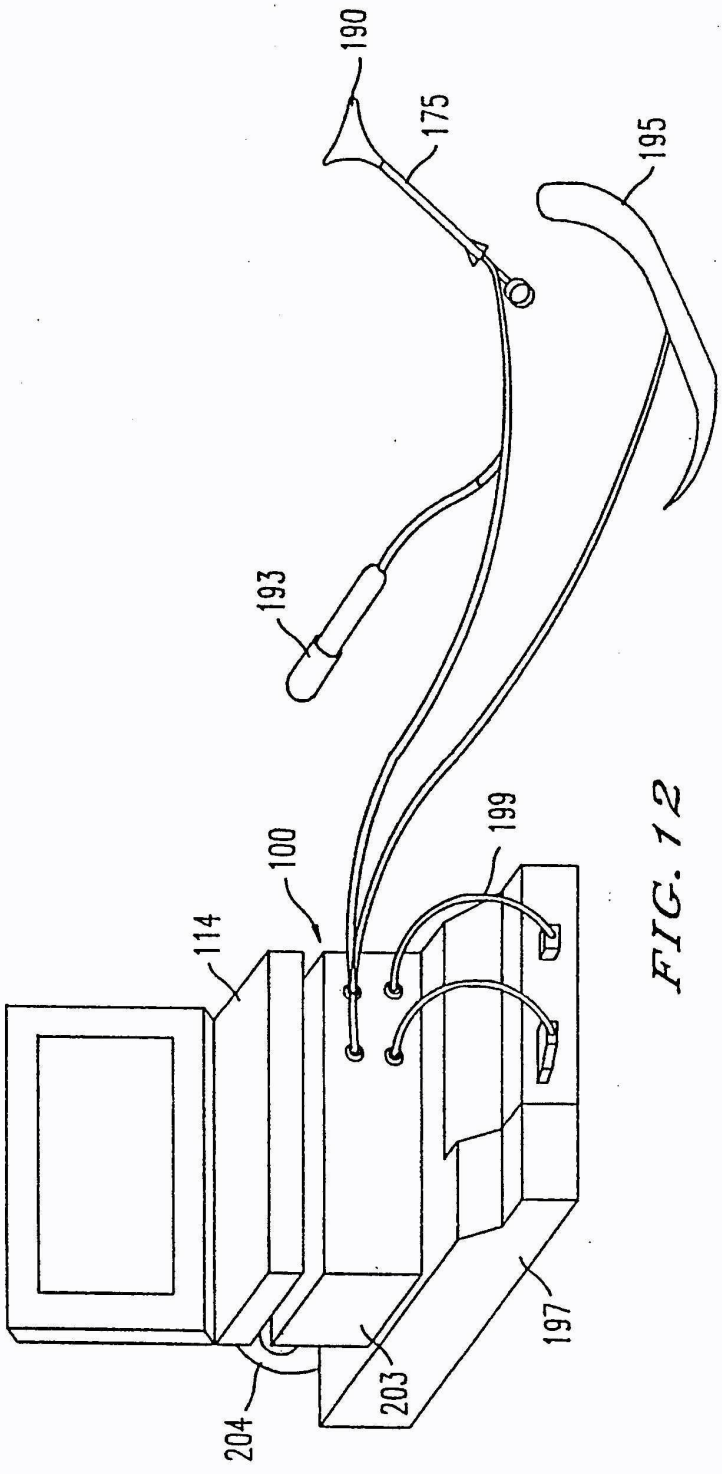
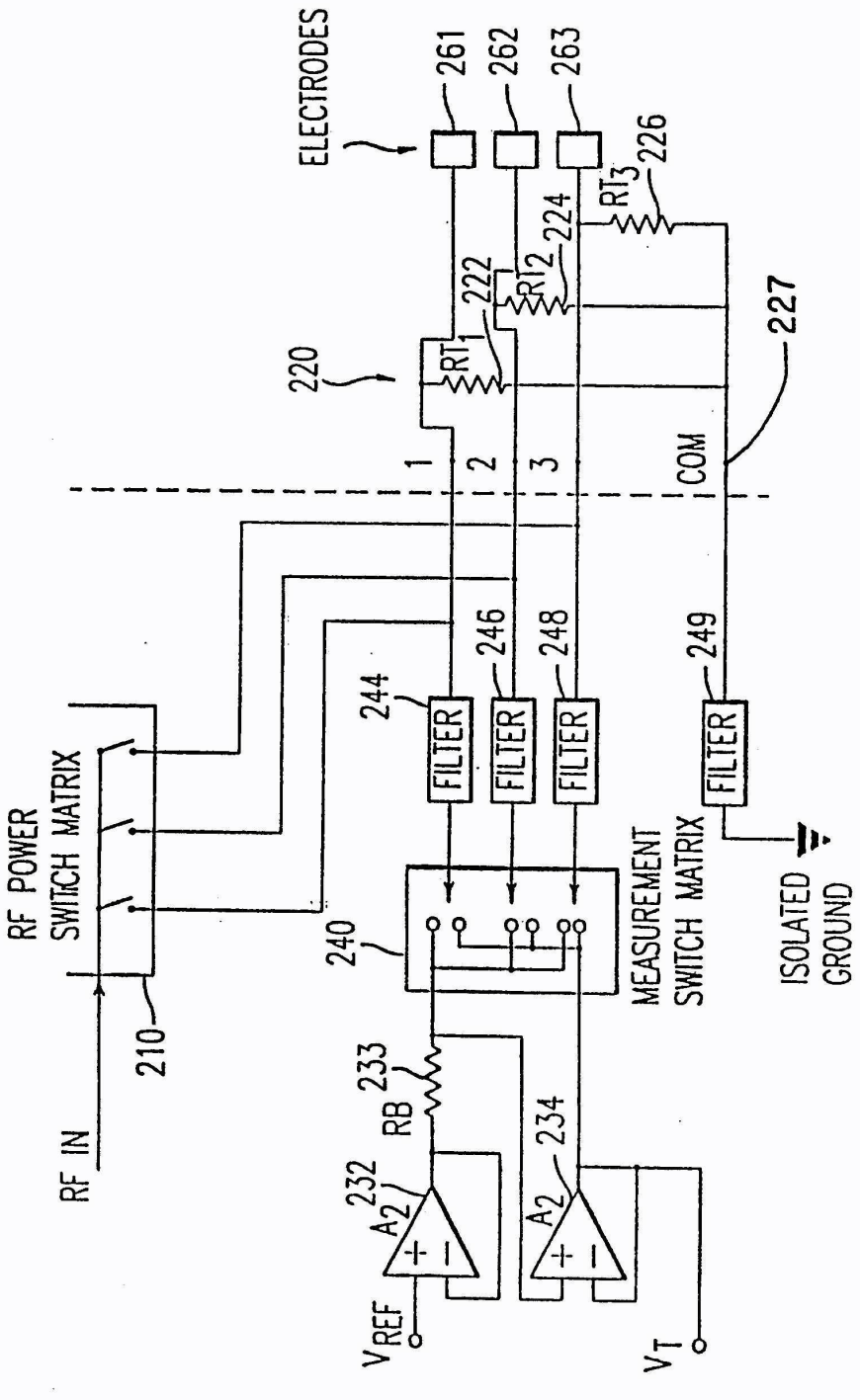


FIG. 12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261
262
263
226
RT3
224
RT2
222
RT1
220
227
1
2
3
COM
246
248
249
244
FILTER
FILTER
FILTER
FILTER
RF POWER SWITCH MATRIX
MEASUREMENT SWITCH MATRIX
ISOLATED GROUND
240
210
RF IN
233
RB
232
234
A2
A2
VREF
VT

FIG. 13

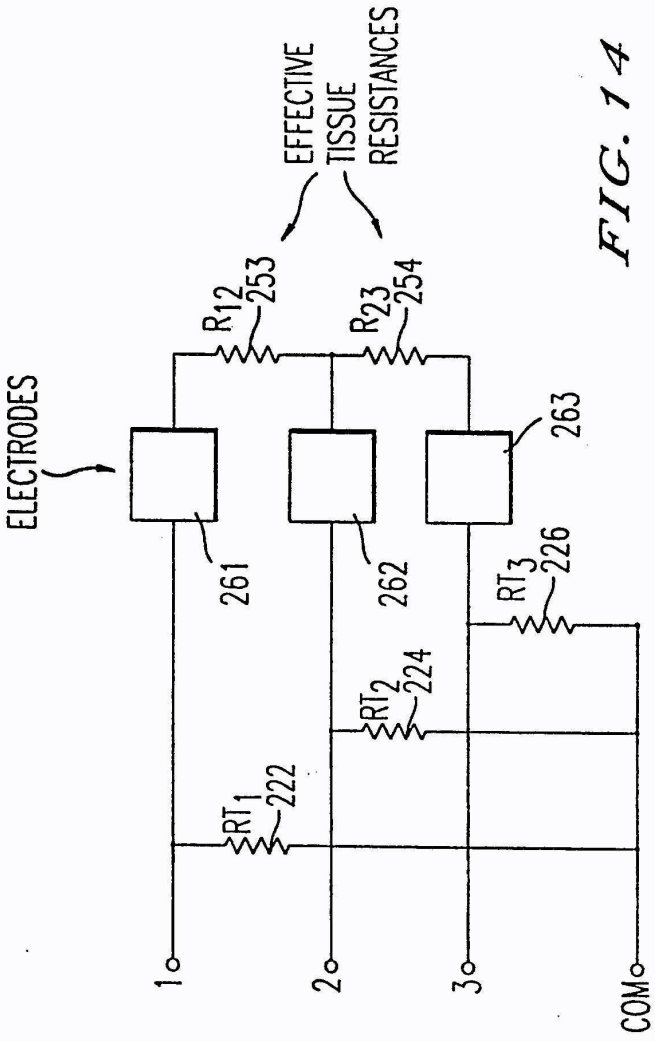
EFFECTIVE TISSUE RESISTANCES
R12 253
R23 254
ELECTRODES
261
262
263
RT3 226
RT2 224
RT1 222
1
2
3
COM

FIG. 14

METHOD AND APPARATUS FOR ENDOMETRIAL ABLATION

CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of application Ser. No. 07/877,567 filed May 1, 1992, now U.S. Pat. No. 5,277,201.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method and an apparatus for in situ destruction of the inner lining of body organs, and more particularly the providing of a selective destruction of the endometrium as an alternative to hysterectomy for treatment of uterine bleeding.

2. Discussion of Background

Prior techniques for removing or destroying the inner lining of body organs have been explored in order to provide for an alternative to surgical removal of the body organs for treatment of diseases and other abnormal conditions. Prior techniques involved the destructive treatment of the inner linings with chemicals and with various forms of thermal energy such as radio frequency, microwave heating, cryotherapy, laser surgery and electrosurgery. Radio frequency and microwave energies have also been applied directly to the linings to generate heat in situ.

One type of thermal destruction is described in U.S. Pat. No. 4,979,949 wherein thermal ablation of the mucosal layer of a gall bladder is accomplished by resistive heating with an RF balloon electrode. Electric current is delivered from the balloon by a conductive expansion liquid filling the balloon. This device has power loss which occurs in the conductive fluid and it cannot be adapted for anything but a single electrode arrangement and it lacks a complete individual power control and/or temperature sensor.

In another example of prior art treatment, balloon catheters have been supplied with a heated fluid for thermal ablation of hollow body organs as described in U.S. Pat. No. 5,045,056. Furthermore, application of microwave and high frequency RF energy to body areas to destroy body tissue, using single electrodes enclosed in expanded balloons have been described in U.S. Pat. No. 4,662,383 and U.S. Pat. No. 4,676,258.

The disadvantage of the procedures occurring in the prior art such as described above include a lack of uniform large area treatment because these procedures involve a lack of uniform control or temperature sensing ability to ensure complete ablation.

Other procedures developed to date involve manual applications of small treatment tools to successive areas of the lining which is an expensive operating room procedure and which, similar to the other previous heat balloon treatments, involve limited assurance of uniform results.

SUMMARY OF THE INVENTION

Accordingly, one object of the present invention is to provide a novel method and apparatus for performing safe and rapid endometrial ablation without the need for visual contact during the ablation of the lining.

It is a further object to provide an apparatus and a method for endometrial ablation which can be carried out on an out-patient basis without requiring the use of an operating room.

The objects of the invention are carried out by a method which utilizes an electrically conductive or conductively coated expandable member conforming to the inner surface of the endometrium. The expandable member is filled with an electrically non-conductive medium and a RF current is passed through substantially the entire surface of the endometrium. The current is sufficient to resistively heat the endometrium in a single Operation to a temperature within a range of between 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining the average temperature of the myometrium at a temperature of substantially 42° C. or less. The RF current has a frequency of at least 250 kHz and less than 100 MHz.

The method according to the present invention involves the insertion of a conductive, expandable member in its unexpanded state into the uterine cavity through the cervical opening and subsequently expanding the member to establish surface contact with the endometrial surface and applying the RF current to the member in its expanded condition.

It is a further object of the present invention to provide that the electroconductive expandable member includes a thin bladder having an array of separate electrodes on one surface and further having a temperature sensor associated with each separate electrode in order to provide a feedback temperature sensor for each electrode. The plurality of separate electrodes are independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature to a desired level.

It is further an object of the present invention to provide electrodes having a specific configuration so that the heating is not concentrated at the edges of the electrode and so that uniform heating is achieved over the entire electrode surface by providing a plurality of throughholes throughout the electrode or by forming the electrode in a pattern of lines, thereby creating a uniform density of edges and equalizing the current density across the surface area of the electrode.

It is a further object of the present invention to provide an electronic control means capable of controlling the output of a conventional electrosurgical power source and delivering power from the power source sequentially, and in a controlled manner, to the electrodes of the balloon.

It is a further object of the present invention to provide a disposable handheld applicator and electrode assembly combination to deliver the ablation device to the uterus and to retract the device upon completion of the ablation.

It is a further object of the present invention to provide an array of separate electrodes and associated separate thermistors on an expandable member with a series of power leads with each power lead delivering power to a single electrode and to its associated thermistor to provide a temperature feedback for temperature regulation of the endometrial ablation.

It is a further object of the present invention to provide an inner lumen having the ability to contain a fiber optic image conduit which serves as a visual aid when placing the device.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete appreciation of the invention and many of the attendant advantages thereof will be

readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

FIG. **1** is a cross-sectional representation of an electroconductive balloon as an expandable member in an expanded format in place in a uterus;

FIG. **2** is a representation of the apparatus of FIG. **1** in an unexpanded condition;

FIG. **3** is an enlarged cross-section illustrating the relationship between a small segment of the uterine endometrium and the expanded member;

FIGS. **4***a–b* is a representation of an embodiment of an expandable member which uses a plurality of surface segments with each surface segment having a separate conductive surface and a temperature sensor;

FIGS. **5***a–b* is a schematic representation of the power control system for the multi-segment element shown in FIG. **4**;

FIG. **6** illustrates an embodiment of the multi-segment element having perforated electrodes with illustrated power traces on the outside surface of the expandable member;

FIG. **7** illustrates thermistor traces and circular wiring jumper mounting pads on the interior of the expandable member;

FIGS. **8***a* and **8***b* illustrates the double-sided electrode/thermistor traces on the respective inside and outside portions of the expandable member of FIGS. **6** and **7**;

FIG. **9** illustrates an embodiment utilizing flat metallized stock material to be adhesively bonded to the expandable member with the material being arranged in a serpentine configuration;

FIGS. **10***a–b* show the bladder device for delivering the expandable member to the uterus;

FIGS. **11***a–c* show the bladder device of FIG. **10** in a retracted position and illustration of the deflated expandable member;

FIG. **12** schematically represents the connection of the bladder device to the power generation source and testing structure;

FIG. **13** is a schematic of an embodiment of the temperature measurement circuitry of FIG. **5**; and

FIG. **14** is an equivalent of FIG. **13** showing effective tissue shunting.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to FIG. **1** thereof, a cross-sectional representation of the invention utilizes an electroconductive balloon as the expandable member with FIG. **2** representing the same apparatus as FIG. **1** prior to inflation of the balloon element. The uterus **2** consists of myometrial tissue **4** surrounding the uterine cavity. The normal uterine cavity or envelope is a flat cavity having approximately the shape of an inverted triangle with the two upper corners communicating with the ovaries by way of the fallopian tubes **6** in the bottom corner opening into the cervical canal **8**. The entire surface of the envelope includes the entrance of the fallopian tubes **6** and the cervical canal **8** which is covered with a thin layer of tissue known as uterine endometrium. The selective destruction of the endometrial cells is the goal of the improved method and apparatus disclosed in this present invention.

The monopolar electrode system developed in conjunction with FIG. **1** expands to conform to the endometrial surface to be treated and this in turn dilates and stretches the endometrium to reduce surface folds. Radio frequency electric current passes through the dilated endometrial surface for a time sufficient to destroy the endometrial cells by elevating the temperature of the endometrium to between 45° C. and 90° C., and preferably within 10 seconds. The temperature is maintained until the endometrial tissue is destroyed which is optimally accomplished by a temperature between 55° C. to 65° C. for up to 10 minutes.

The electric current passes through or along the surface of the expandable member and the interior of the expandable member is filled with an electrically non-conductive substance such as a fluid or gas. The expandable member can be any material or article which can be compressed or otherwise prepared in a small diameter configuration for insertion through the cervix and expanded or inflated after insertion to provide the dilation. This expandable member establishes direct electrical connection or capacitive coupling with the endometrium. A second electrical contact can occur by way of grounding plates or patches which contact a large area of the patient's skin in order to complete the electrical circuit.

Electric current flowing through the tissue causes resistive heating. The power density diminishes with distance from the electrode as the reciprocal of the fourth power of the distance. Thus, any heat generated is focused in the endometrium and the immediately surrounding muscular tissue which in the particular case of the present invention is the portion of the myometrium in contact with the lining. Because the myometrium **4** is highly vascularized, heat removal occurs rapidly. As a result, the temperature of the endometrium **12** can be heated to a destructive temperature faster than the myometrium **4** and the rest of the uterus. Therefore, because of this temperature relationship, endometrial ablation can be safely accomplished as a simple medical procedure using local anesthesia. Furthermore, it can be a service made available at a fraction of the cost of prior art systems with less hazard than other endometrial ablations.

The inflatable balloon or bladder **14** is inserted into the uterine cavity **15** as shown in FIG. **2** and subsequently the inflation of the balloon occurs with a gas or a non-conductive liquid so that it extends and fills the uterine cavity conforming to the expanded surface as shown in FIG. **1**. Portions of the balloon **14** extend into the entrance to the fallopian tubes **6** and extend along the entire endometrial surface **12** to the cervix **8**. The balloon is attached to and forms a fluid-tight seal with the tube **16** which encloses a smaller fluid delivery tube **18** as well as an electrical cable **20** containing leads for the conductor as well as additional leads for the sensors. A plurality of temperature sensors **24** are shown attached to the inner surface of the balloon. Alternatively, this lead configuration can be replaced by lead pairs **22** for each sensor. The temperature sensors **24** are conventional thermistors or thermocouples and are positioned on zones of the balloon which will contact areas of the endometrial surface which are most sensitive to overheating. The temperature sensors can also be fiber optic temperature sensors. The fluid delivery tube **18** is connected to a source of gas or liquid through a conven-

tional fluid control system which will be later illustrated in conjunction with FIG. **13**.

The FIG. **3** is an enlarged cross-section illustrating the relationship between a small segment of uterine endometrium and the expandable balloon element of the FIG. **1**. The endometrial lining **12**, supported on the myometrium **4**, is typically an irregular surface even after it is extended by the inflated balloon **14**. Electrical contact between the conductive surface **35** on the outer surface of the balloon **14** and the endometrium **12** can be improved by covering the outer surface of the balloon **14** with a conventional electroconductive solution, paste or gel **37** which is physiologically non-toxic and non-irritating. Suitable electroconductive media including the known types of gels and pastes used as surface coatings for defibrillators may be used. Examples of suitable conductive gels are carboxymethylcellulose gels made from aqueous electrolyte solutions such as physiological saline solutions and the like. The electroconductive solution, paste or gel enhances electrical contact between the balloon and the endometrium by filling the pores of the balloon surface and the irregularities in the endometrial surface.

The expandable balloon or bladder can be an elastomeric polymer such as a natural or synthetic rubber made conductive by mixing the polymer with electroconductive particles such as carbon or conductive metal particles. Alternately, it may be made conductive by a surface coating of electroconductive material such as an electroconductive gel, or a conductive metal coating on the outer or inner surface of the balloon or bladder wall. Electroconductive coating can be applied to organic polymer surfaces by conventional vapor deposition, electrical depositions, sputtering and the like.

A preferred balloon comprises a thin, non-extensible polymer film such as a polyester or other flexible thermoplastic or thermosetting polymer film, for example, having a conductive metal coating on the outer or inner surface thereof. The films form a non-extensible bladder having a shape and size, in its fully expanded form, which will extend the organ and effect contact with the endometrial lining to be destroyed. The inner surface of the non-extensible bladder can be coated with electroconductive material which will capacitively couple to the endometrium provided that the bladder wall thickness is less than approximately 0.25 mm.

The surface of the expandable member can be an open-cell, porous material such as a foam or similar caged network of material which can hold a quantity of the electroconductive solution, paste or gel required to secure satisfactory electrical contact with the opposed endometrial surface. The surface can be coated with or impregnated with the electroconductive substance.

FIG. **4** illustrates an embodiment using a balloon with a plurality of surface segments as the expandable bladder **39**. Each of the surface segments has a conductive surface and a temperature sensor. In this particular embodiment, the balloon has a segmented electrode coating of electroconductive metal on either the inner or the outer surface to permit controlled delivery of power to each segment. Each segment **40** is electrically connected through conventional leads to a power source (not shown in FIG. **4**). Each conductive segment **40** also has a thermistor **42** which is connected through conventional leads to a switch matrix. FIG. **4B** illustrates a top view of the bladder **39** and particularly features a lumen **44** extending through the center of the bladder **39**. The lumen allows for light guides to be inserted through the center of the electrode. In other words, there is an inner lumen tube **44** attached to the center of the flat film.

FIG. **5** is a schematic representation of the power source controller and the switch matrix for the multi-segment balloon discussed above in conjunction with, for example, FIG. **4**. The electrical leads connect to the electro-thermistor pairs of the bladder of FIG. **4** by way of connectors **138** as shown in FIG. **5**. The thermistor leads are connected to the matrix switch bank **134** and the electrode leads are connected to the switch bank **136**. Each thermistor (FIG. **4***a*) **42** is sampled by means of the temperature measurement circuitry **128** and the isolation amplifier **126** before being converted in the converter **116** and fed to the computer **114**. The temperature measurement circuitry compares the measured temperature with a thermistor reference voltage **132**. The electrode switch **136** is controlled in response to the output of the computer **114** by means of the opto-isolators **130**. Input power from the RF input passes through the overvoltage and overcurrent protector **110** and is filtered by the bandpass filter **122** before being subjected to overvoltage suppression by the suppression unit **124**. The voltage is isolated by means of the transformers **139**, **140** and **142** with the transformer voltages V_i and V_v from the transformers **140** and **142** being converted by the RMS-DC converters **118** into an RMS voltage to be fed to the converters **116**. Prior to conversion, the signals V_i and V_v are also fed to a high-speed analog multiplier **120** RF control from computer **114** is provided through interface **112**.

A variation of the electrode structure of FIG. **4** is shown in FIG. **6** wherein there are perforated electrodes **150** illustrated with their power traces **152**. This particular electrode bladder of FIG. **6** is shown with the perforated electrode **150** on the exterior of the bladder.

FIG. **7** illustrates thermistor common-side traces **154** on the interior of the bladder with circular wiring jumping pads **156** with mounting sites **157** serving as the base for the thermistors. The common-side traces provide power for both the electrodes and the associated thermistor. The FIG. **7** illustrates both interior sides of the bladder.

FIGS. **8***a–b* illustrates both the outside and the inside of a double-sided electrode with thermistor traces having perforated electrodes **160** on the outside and thermistor wiring pads **162** and electrode power leads **164** as well as thermistor mounting sites **166** on the inside. The connection between the inside and outside of the bladder is shown by the continuity labeled Via in the FIGS. **8***a* and **8***b*. FIG. **8***b* specifically shows a cross-sectional view of the bladder with the electrode **160** on the top or outside surface and the power traces **164** and thermistor wiring pad and mounting site **166** on the lower or inside surface. FIG. **8***b* illustrates the mounting of the thermistor **163** on the mounting site **166** with a connection between the power trace **164** and the thermistor **163** being made by the thermistor lead **169**. FIG. **8***b* clearly illustrates that all except one of the holes in the perforated electrode **160** have a depth which reaches to the substrate or bladder **174**. The one hole labelled Via extends through the entirety of the bladder as an electrical connection between the perforated electrode **160** and the power trace **164** on the bottom or inside surface. The FIG. **8***a* embodiments corresponds to a combination of the inside illustration of the power traces and the bonding surfaces from FIG. **7** along with the perforated electrode of FIG. **6** with the exception that FIG. **8***a* has

the power traces on the inside surface whereas the embodiment of FIG. **6** has the power traces for the perforated electrodes on the outside surface.

Each of the views of FIGS. **6**, **7** and **8**, whether on the inside or the outside must be understood to represent only two surfaces of a bladder which must necessarily have four surfaces. The bladder, prior to inflation, can be envisioned as triangular with two outside triangular surfaces (top and bottom) and two inside triangular surfaces prior to inflation.

A further variation of the electrode structure is shown in FIG. **9** which illustrates a flat metallized stock material adhesively bonded as electrodes **170** and **172** to the outside of both the top and the bottom of the bladder. The electrodes, which are metallized and adhesively bonded, form a serpentine electrode pattern in order to promote uniform heating of the area.

FIGS. **10***a* and **10***b* illustrate the bladder application device which is used to insert the bladder electrode constructed in accordance with any one of the embodiments discussed above. FIG. **10***b* is a side view of the application device illustrating a sheath applicator with a main tube and a shrink wrap covering the wiring leads. A fiber bundle is located in the center of the applicator which would be connected through the lumen illustrated in FIG. **1**, for example. The applicator device **175** has an inflation inlet **176** and an electrode wiring insertion port **177** as well as the optical viewing fiber inlet **178** through a lumen. Movement of the bladder electrode **180** is controlled by the alignment guide and the sheath retraction knob **181** acting in conjunction with a thumb detent **182**. The applicator of FIG. **10***a* shows the bladder electrode in an extended but unexpanded position.

The FIGS. **11***a–c* illustrate the bladder device of FIG. **10** in a retracted position with FIGS. **11***b* and **11***c* being taken at the cross sections titled A—A′ and B—B′ respectively. FIG. **11***c* illustrates the position of the deflated bladder with respect to the main tube in the retracted position at line B—B′. The remaining features of the applicator **175** remain as indicated with respect to FIG. **10**.

An illustration of the connection of the application device **175** and the electrode balloon **190** in accordance with any one of the embodiments of the FIGS. **6–9** is illustrated in FIG. **12**. An inflation pump **193** provides the medium for the expansion of the balloon **190** while the electrode belt **195** provides the reference electrode for connection to the control system **100**. RF generator **197** serves as the RF input power for the control system schematic of FIG. **5** by means of electrosurgical interface cables **199**. The control module **203** and interface control **204** connect with computer **114**.

Once the electrode system and the control system of FIG. **12** and FIG. **5** are connected, the RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature up to a desired level. The system accomplishes this in an automated manner based upon the output from the RF generator **197** which is a conventional electrosurgical power supply. As discussed previously, the electrodes may have a variety of specific configurations and heating is concentrated in the endometrium at the surfaces of the electrodes due to the various illustrated electrode configurations in order to provide uniform heating. An example of the concentration of the heat over the entire surface of the electrode is available from the embodiment wherein holes are provided through the electrode as shown in FIGS. **6** and **8**. Uniform heating is also obtained by extending the electrodes in a pattern of lines such as the serpentine pattern structure of FIG. **9**.

As a result of these kinds of constructions, the treatment method of the present invention as well as the electrode elements provide an increased current density as a function of the "electrode edge length" available for heating. Furthermore, as discussed previously, the electrodes can be on the outer surface of the bladder while the power traces, thermistors, and thermistor leads can be on the other surface of the bladder.

In the embodiments of FIGS. **6–9**, the various electrode pattern feature common power traces for both the electrodes and the associated thermistors. That is, one power lead provides the power for an individual electrode as well as its associated thermistor thereby saving in the construction of the bladder electrodes by reducing the number of required thermistor leads by one-half. In such embodiments, each electrode has a corresponding thermistor lead in common with the RF power lead. The second leads from all thermistors are then connected together to form a thermistor common as shown for example in the FIGS. **7** and **8***a*. This arrangement provides the advantage that it only requires N+1 leads to drive an ablation balloon with N electrodes and N thermistors. Because of this construction, however, the temperature measurement circuitry **128** of FIG. **5** has additional requirements beyond the construction with a separate power lead for each thermistor and for each individual electrode. The construction with separate power leads for the electrodes and the thermistor are well known and any one of a variety of temperature measurements schemes for individual electrodes could be utilized.

The specialized requirements brought about by using a common power lead for each electrode and each thermistor are met by the embodiment shown in the FIG. **13**. In FIG. **13**, RF power is selectively applied through switch matrix **210** so that it can be applied to selected electrodes. The electrode/thermistor circuitry is represented on the right hand side of the Figure generally as **220** with a particular example being given by three electrodes and three thermistors represented by resistors **222**, **224** and **226**. A reference voltage Vref is buffered by an operational amplifier follower **232** and passes through resistor **233** before entering the measurement switch matrix **240**. The output of resistor **233** is buffered by operational amplifier **234**. Outputs of the measurement switch matrix **240** are fed through the filters **244**, **246** and **248** which represent low pass filters which block high frequency RF but pass DC and very low frequency voltages.

The balloon thermistor common lead **227** passes through the filter **249** to ground.

During operation, RF power is applied to a particular desired electrode or electrodes by operations of the RF power switch matrix **210**. Measurement of thermistor resistance **222**, **224** or **226** is independent of the particular electrodes connected to the RF power. In order to provide a measurement of RT**1** (**222**), measurement switch matrix **240** is set up to connect lead **1** to the right hand side of resistor **233** while all other leads are set to be connected to the output of the follower **234**. This particular set up and arrangement forces the voltage VT to be equal to V_{REF} RT1/(Rb+RT1). Therefore this allows the measurement of RT**1** due to the known value of Rb and V_{REF}. Because the other leads **2**, **3** from

the circuitry **220** are held at the same voltage by the follower **234**, there are no voltage differences between any of these leads and therefore no current will flow between them.

This lack of a current between leads is extremely important because the tissue which contacts the electrodes cause an effective shunt current path that would otherwise affect the measured voltage VT, without the circuitry of FIG. **13**.

This effective shunting by the tissue is illustrated by the equivalent circuit of FIG. **14** which shows effective tissues resistances **253** and **254** connected between electrodes **261**, **262** and **263**.

The bladder electrodes are constructed in accordance with a method wherein a double-sided thin flat film is plated on one side to increase the electrode thickness and a deposit mask is provided for an electrode pattern on the thick side using lithographic techniques. Then a mask is deposited for the conductors which lead to the temperature sensing elements on a second side. Subsequently, non-masked conductors are etched away leaving the desired pattern. In an alternate embodiment, the conductive patterns for the electrodes and conductors leading to the temperature sensing elements could be directly deposited using vapor or other deposition techniques.

The thermistors (FIG. **4***a*) **42** are provided using surface mounting techniques and the attached inner lumen is provided at the center of the flat film. The balloon is then folded and sealed to the main tube at the proximal end with the inner and outer concentric tubes sliding with respect to each other as illustrated in the FIG. **10**. Subsequently, conductors are brought to the outside of the main tube to the end of the device near the handle of the applicator. The outer tube is placed over the conductor and heat-shrunk as shown in FIG. **10***b*. Finally, the handle of the applicator of FIG. **10** or FIG. **11** is assembled.

Other forms of providing an electrode balloon may be used such as utilizing a blow molded preform or the formation of the balloon with copper on polyimide conductive elements on the surface of a compliant balloon. Furthermore, this balloon may be formed as a "sock" to fit over the inner latex balloon with the sock being a compliant device. Other anticipated forms of an electrode balloon structure include the use of the plated or etched wiring all the way from the balloon itself down to the handle.

Utilizing the present invention allows for the use of low accuracy thermistors wherein calibrations can be stored in memory chips in the handles of the device. The attachment of the electrodes to the bladder can be accomplished by conductive adhesive or by soldering.

The applicator of FIGS. **10** and **11** can be deployed by pulling the front end of the balloon back inside and collapsing the balloon around it. In order to expedite the deployment, the pattern can be formed with particular kinds of spines for the sheath in order to aid in the folding of the patterned electrode within the applicator.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed and desired to be secured by Letters Patent of the United States is:

1. An endometrial ablation apparatus for selectively destroying the endometrial lining of a body organ, said apparatus comprising:

an electroconductive, expandable electrode means for effecting electrical contact with said endometrial lining to be destroyed, said expandable electrode means containing an electrically non-conductive expansion medium for extending said electrode means to provide said effected electrical contact with said organ;

a radio frequency power means connected to said expandable electrode means at a frequency greater than 250 kHz for selectively providing current to said electrode means to heat said endometrial lining to a uniform temperature of between 45° C. to 90° C.

2. An endometrial ablation apparatus according to claim **1** wherein said frequency is in a range between 250 kHz and 100 MHz.

3. An endometrial ablation apparatus according to claim **1** wherein said expandable electrode means include an electroconductive balloon and an expansion fluid inlet which is connected to the electroconductive balloon and wherein said balloon is filled with said electrically non-conductive expansion medium.

4. An endometrial ablation apparatus according to claim **3** wherein said balloon is an electroconductive elastomer.

5. An endometrial ablation apparatus according to claim **1** wherein said expandable electrode means is a non-extensible bladder coated with electroconductive material.

6. An endometrial ablation apparatus according to claim **5** wherein an inner surface of said non-extensible bladder is coated with electroconductive material and the bladder wall thickness is less than 0.25 mm.

7. The apparatus according to claim **1** wherein said expandable electrode means includes at least one temperature sensing means.

8. The apparatus according to claim **1** wherein the radio frequency power means includes an output and the apparatus further includes a control means for controlling the output of said radio frequency power means to said expandable electrode means.

9. The apparatus according to claim **8** wherein said control means includes at least one thermistor, having an output, for measuring a temperature of said expandable electrode means and wherein said control means includes means for comparing the output of said at least one thermistor with a reference value and wherein said control means provides an output in response to said means for comparing in order to control the output of said radio frequency power means.

10. The apparatus according to claim **1** wherein said expandable electrode means includes an expandable member and a flat metallized electrode, said expandable member having an outside, said flat metallized electrode being attached to said outside, and wherein said metallized electrode is arranged in a serpentine manner to form a patterned electrode.

11. The apparatus according to claim **1** wherein said radio frequency power means provides current to said electrode means to heat said endometrial lining to a uniform temperature of between 45° C. to 90° C. for a period of ten minutes or less.

12. The apparatus according to claim **1** wherein said expandable electrode means is provided with a plurality of separate electrodes and a thermistor associated with

each of said plurality of separate electrodes and further including a plurality of electrode power leads each one of said leads being electrically connected to a respective one of said plurality of separate electrodes and a respective one of said thermistors.

13. The apparatus according to claim **12** further including a temperature measurement circuitry including a first switch matrix means for selectively applying RF power to at least one of said plurality of electrode power leads, a first reference voltage point, a second reference voltage point and a second switch matrix means for connecting a selected one of said plurality of electrode power leads to said first reference voltage point while simultaneously connecting all other ones of said electrode leads to said second reference voltage point.

14. An endometrial ablation apparatus for selectively destroying the endometrial lining of a body organ, said apparatus comprising:

an electroconductive, expandable electrode means for effecting electrical contact with said endometrial lining to be destroyed, said expandable electrode means containing an electrically non-conductive expansion medium for extending said electrode means to provide said effected electrical contact with said organ, said expandable electrode means being a non-extensible bladder provided with a plurality of separate electrodes; and

a radio frequency power means connected to said expandable electrode means at a frequency greater than 250 kHz for selectively providing current to said electrode means to heat said endometrial lining to a uniform temperature of between 45° C. to 90° C., said radio frequency power means having an output.

15. The apparatus according to claim **14** wherein each of said electrodes includes a thermistor.

16. The apparatus according to claim **15** further including a control means responsive to an output of each of said thermistors for controlling the output of the said radio frequency power means to said expandable electrode means.

17. An electrically conductive expandable electrode assembly for providing electrical contact with an endometrial lining of a uterus for the purpose of destroying said endometrial lining, said assembly comprising:

an expandable bladder having an-inner surface and an outer surface, one of said inner and said outer surface being provided with a plurality of separate electrodes and the other of said inner and outer surface being provided with a plurality of thermistors corresponding to each of said plurality of electrodes;

each of said plurality of electrodes further comprising a plurality of holes with one of said plurality of holes of each electrode extending through said bladder from said outside surface to said inside surface and said extended holes providing electrical continuity between said electrodes and said other surface;

said other surface further including a plurality of power leads, each lead being electrically connected to a corresponding one of said electrodes, said leads each extending from one extremity of said bladder to a respective one of said extended holes, each said power lead also extending to a respective one of said thermistors,

whereby the relationship between the plurality of holes in each of said electrodes and said power leads provides for uniform heating on a surface of each of the respective electrodes.

18. The expandable electrode assembly according to claim **17** wherein each of said thermistors is further connected to a common ground lead on said other surface.

19. An ablation method for selectively destroying the lining of a body organ having a supporting mass under the lining, said method comprising the steps of:

passing a radio frequency current having a frequency of at least 250 kHz from an expandable member conforming to the lining and filled with an electrically non-conductive medium, wherein said current is passed through a portion of the lining to resistively heat in a single operation the lining to a temperature within a range from 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining an average temperature of the supporting mass at a temperature below approximately 42° C.;

monitoring the temperature of the lining and reducing said current when said monitored temperature exceeds a predetermined value.

20. The method of claim **19** wherein the body organ is a uterus, the lining is the endometrium of the uterus, and the supporting mass is a myometrium of the uterus.

21. The method of claim **19** wherein said portion of the lining includes the entire inner surface of the lining.

22. An ablation method of claim **19** wherein the method comprises an endometrial ablation method for selectively destroying the endometrial lining of a uterus having a myometrium layer under the endometrial lining, said endometrial ablation method comprising the steps of:

passing a radio frequency current having a frequency of at least 250 kHz from an expandable member conforming to an inner surface of the lining and filled with an electrically non-conductive medium, wherein said current is passed through substantially the entire inner surface of the lining to resistively heat in a single operation said lining to a temperature within a range from 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining an average temperature of the myometrium at a temperature below approximately 42° C.;

monitoring the temperature of the surface of said lining and reducing said current when said monitored temperature exceeds a predetermined value.

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