No. 16-360

IN THE

Supreme Court of the United States

MYLAN PHARMACEUTICALS INC. & MYLAN INC.,
Petitioners,

v.

ACORDA THERAPEUTICS INC., ALKERMES PHARMA IRELAND LIMITED,
Respondents.

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ASTRAZENECA AB,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* OF GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae the Generic Pharmaceutical Association ("GPhA") is a non-profit, voluntary association comprised of nearly 100 manufacturers and distributors in the generic pharmaceutical industry, which in turn accounts for over 88 percent of prescriptions dispensed in the United States each year. GPhA's members provide American consumers with safe and cost-effective medicines that are bioequivalent to, and have the same safety, efficacy, and therapeutic benefit as, their brand-name counterparts. These products significantly improve public health while cutting annual healthcare costs by billions of dollars.

GPhA's core purpose is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. Toward this end, GPhA advances the interests of its members through initiatives in the scientific, regulatory, federal and state forums and in the public affairs arena. GPhA also regularly participates as amicus curiae in cases before the Federal Circuit and the Supreme Court.

This case concerns where a plaintiff may properly hale a defendant Abbreviated New Drug Application ("ANDA") filer into court under the Drug Price Competition and

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae, or its counsel, made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief, either by express written consent or by filing a letter documenting consent with the Court.

Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or the "Act"). For reasons Petitioners have explained, the Federal Circuit's decision is erroneous on multiple levels. GPhA fully endorses the petition for certiorari and the reasons stated therein for granting certiorari. GPhA submits this brief to emphasize several particularly serious and critical flaws in the Federal Circuit's reasoning that cannot be squared with the Hatch-Waxman Act's mechanism for suits following ANDA filings. GPhA's expertise in these matters will aid the Court in understanding the purpose of the Hatch-Waxman Act and provide necessary perspective on the significant implications of this case for the generic pharmaceutical industry and the United States market for prescription drugs.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

In an effort to evade the clear import of this Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), the Federal Circuit has carved out a special exception to this Court's Due Process precedents that applies just to Defendants sued for patent infringement under the Hatch-Waxman Act. This new "ANDA exception" purports to ground the exercise of nationwide jurisdiction over a defendant drug company based on nothing more than the filing of an ANDA, which the Federal Circuit assumes indicates "planned, non-speculative harmful conduct," *i.e.*, infringing future sales. App.13.

This is mistaken for two reasons. *First*, the future infringing sales will almost never occur. Because of the automatic 30-month stay of FDA approval provided by the

Hatch-Waxman Act, in the vast majority of cases there will either be an injunction against sales or a judgment of non-infringement or invalidity prior to any sales of a defendant's ANDA product. *Second*, the Federal Circuit was wrong to assume that the filing of an ANDA reliably indicates future marketing, as there are many reasons an ANDA filer may ultimately not market its product.

Finally, the Federal Circuit's novel rule ensures the continued, unwarranted concentration of ANDA litigation in just two district courts. Between 2009 and 2015, 73 percent of all ANDA suits were filed in either the District of Delaware or the District of New Jersey. This result was never intended by Congress, and this Court should be skeptical of a rule that perpetuates these unintended specialist ANDA courts.

The question presented by the Petition is undoubtedly important—whether an ANDA defendant is governed by the generally applicable principles of Due Process, or by a judicially invented "ANDA exception" to those principles. The GPhA respectfully submits that this Court's review is needed.

ARGUMENT

I. Overview of the Statutory Scheme.

The Hatch-Waxman Act was designed by Congress to "to speed the introduction of low-cost generic drugs to market." *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). To achieve this goal, the Act authorized generic companies to file a less expensive *Abbreviated* New Drug Application ("ANDA"), which

removed the need for developers of generic drugs to repeat the studies conducted by their branded counterparts and outlined the abbreviated pathway that created the modern generic drug industry. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (citing 21 U.S.C. § 355). This abbreviated pathway includes a mechanism for branded and generic pharmaceutical companies to timely litigate disputes relating to patent infringement, validity, and enforceability. *See id.* Under the Act, ANDA filers may be sued for patent infringement based on the "highly artificial act of infringement" of "submitting" an ANDA. *Id.* at 678; *see also* 35 U.S.C. § 271(e)(2).

As part of this process, if an ANDA filer seeks approval of a generic product prior to the expiration of a branded drug's listed patents, the Hatch-Waxman Act permits the ANDA filer to include in its application a certification (a "paragraph IV certification"), stating that any such patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

If the patent owner then brings suit against the ANDA applicant, FDA approval of the ANDA product is automatically stayed until the court rules that the patent is invalid, unenforceable, or not infringed, or until the expiration of 30 months.[2] *Eli Lilly*, 496 U.S. at 677–78 (citing 21 U.S.C. §§ 355(c)(3)(C), 355(j)(4)(B)(iii).

This 30-month stay is intended to allow the district court to adjudicate validity and infringement *prior* to the sale of the generic drug product. *See id.* at 678 ("Quite

2. The stay can also be extended by the district court under certain circumstances. *See* 21 U.S.C. § 355(c)(3)(C).

obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.") (citing 35 U.S.C. § 271(e)(4)(C)). Thus, in the vast majority of ANDA cases, there will never be an infringing sale because, among other reasons, the Court will adjudicate the issues of infringement and validity before a single dose of the defendant's generic drug is ever sold.

II. The Federal Circuit's new standard for personal jurisdiction implicates a question of exceptional importance and is based on the erroneous premise that an ANDA filing reliably indicates planned future infringing sales.

The generic drug industry is vitally important to the Nation's healthcare system and its economy. In 2014, 3.8 billion prescriptions were filled in the United States with generic drugs, accounting for 88 percent of all prescriptions filled. *See* GPhA Report, Generic Drug Savings in the U.S. at 1 (2015).[3] And over the last 10 years, generic drugs have been responsible for $1.68 trillion in healthcare system savings, including $76.1 billion in savings for the United States Government's Medicare program in 2014 alone. *Id.* at 1, 5-6.

This case profoundly impacts this vital industry. The Federal Circuit's decision, in effect, subjects every ANDA filer to nationwide jurisdiction for Hatch-Waxman Act litigation in violation of generic defendants' due process rights. As a result, an ANDA filer cannot predict where it will be subject to suit.

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3. *Available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf (last visited Oct. 20, 2016).

A. The Federal Circuit's decision sharply conflicts with *Daimler*, which dramatically restricted the scope of nationwide jurisdiction.

The Federal Circuit's new "ANDA exception" ignores the clear teachings of this Court. Just two years ago, this Court decided *Daimler AG v. Bauman*, where it described a similar assertion of nationwide jurisdiction as "unacceptably grasping." 134 S. Ct. at 761. Although *Daimler* addressed general jurisdiction, it made crystal clear that a rule subjecting defendants to nationwide jurisdiction based on nationwide sales does not comport with due process because it does not "permit out-of-state defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *Id.* at 762 (quotation marks omitted), *see id.* at 750–51 (calling the exercise of jurisdiction in that case "exorbitant" because "the same global reach would presumably be available in every other State in which [defendant's] sales are sizable").

Prior to *Daimler*, ANDA applicants were subject to broad general jurisdiction. Thus the result of *Daimler* in the ANDA context should have been dramatic. But instead, there was no change. While paying lip service to *Daimler*, the Federal Circuit ignored *Daimler's* guidance by preserving the same nationwide jurisdiction through the judicial creation of a special ANDA-only rule for specific jurisdiction based only on speculative future conduct, *i.e.*, assumed future sales. This "ANDA exception" is an improper judicial invention that is not supported by the text, structure, or legislative history of the Hatch-Waxman Act.

First, nothing in the text of the Hatch-Waxman Act indicates that Congress intended to create special jurisdictional rules for ANDA filers. The Act simply makes the filing of an ANDA an act of infringement to allow for the adjudication of patent infringement and validity prior to the approval of a generic drug. *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly*, 496 U.S. at 678 ("Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.").

Second, the "ANDA exception" does not comport with the structure of the Hatch-Waxman Act. The Federal Circuit purports to justify nationwide jurisdiction over ANDA filers based on the filer's "planned, non-speculative harmful conduct," *i.e.*, infringing future sales. App.13. But this overlooks a key point: The Hatch-Waxman Act's carefully balanced framework ensures that in the vast majority of cases there will never be an infringing sale.

When a patent-holder files suit against an ANDA applicant under the Hatch-Waxman Act, the FDA is barred for thirty months from approving the ANDA. *See* 21 U.S.C § 355(j)(5)(B)(iii); *Eli Lilly*, 496 U.S. at 678. The intent of this 30-month stay is to allow the Court to adjudicate validity and infringement *prior* to the sale of the generic drug product. *See Eli Lilly*, 496 U.S. at 678; 35 U.S.C. § 271(e)(4)(C). Thus the Hatch-Waxman Act does not envision damages as a typical remedy, unlike the general patent infringement statute. *See Eli Lilly,* 496 U.S. at 678 ("Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in subsection (e)(4). Monetary damages are permitted only if there has been 'commercial manufacture, use, or sale.'"). Indeed, it has been reported that since 2000, only

five ANDA cases have resulted in an award of damages.[4] For comparison, 2,249 ANDA cases were filed between January 1, 2009 and December 31, 2015 (reflecting approximately 600 applications).[5]

Thus, under the Hatch-Waxman framework, the district court may find the patent valid and infringed, in which case the generic company will not sell its generic product until after the relevant patents have expired (or the generic company takes a license). Or, if the district court finds that the ANDA product does not infringe any valid patent claim, then any sales will be non-infringing sales. Either way, the statutory scheme ensures that in the vast majority of Hatch-Waxman cases, there will never be an infringing sale.

Third, the Federal Circuit's "ANDA exception" is contrary to the legislative history of the Act. In justifying its novel jurisdictional rule, the Federal Circuit reasoned that "upholding personal jurisdiction will serve the interests of the plaintiffs and the judicial system in efficient resolution of litigation, because multiple lawsuits against other generic manufacturers on the same patents are pending in Delaware." App.17. Whatever the merits of this proposition, it is not what Congress intended. As

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4. *See* Brian C. Howard & Jason Maples, Lex Machina, Hatch-Waxman/ANDA Litigation Report 2015, at 18 (Apr. 2016); *see also* Lex Machina, Pharmaceutical Patent Litigation Filings Have Risen Significantly since 2014, According to Lex Machina's 2015 Hatch-Waxman/ANDA Report, *available at* https://lexmachina.com/media/press/pharmaceutical-patent-litigation-filings-risen-since-2014 (last visited Oct. 20, 2016) (summarizing the 2015 report).

5. Brian C. Howard & Jason Maples, Lex Machina, Hatch-Waxman/ANDA Litigation Report 2015, at 1 (Apr. 2016).

Congress explained, "[i]n the event of multiple ANDA's certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation." H.R. Rep. No. 98-857(I), at 28 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2661 (emphasis added). Thus Congress considered the very concern that animates the Federal Circuit's reasoning and concluded that ANDA lawsuits would and should be subject to the same rules as any other lawsuit, using the existing multi-district litigation apparatus.

In short, without any support in the text—and in the face of the contrary structure and legislative history of the Hatch-Waxman Act—the Federal Circuit created a special exception to this Court's generally applicable Due Process precedents that only applies to defendants in ANDA lawsuits. This novel judicial invention requires this Court's review.

B. The Federal Circuit's "ANDA exception" is based on the mistaken assumption that an ANDA filing reliably indicates planned future infringing sales.

The Federal Circuit's novel "ANDA exception" is propped up on a single key assumption: That "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." App.8. But this assumption is wrong.

As an initial matter, and as explained above, the structure of the Hatch-Waxman Act ensures that in the vast majority of cases there will never be an infringing sale because all infringement claims will be resolved before an ANDA product ever reaches the market. *See supra* at 3–4, 7-8.

Additionally, even in the absence of litigation, the mere filing of an ANDA does not reliably indicate planned future infringing sales, as the Federal Circuit assumed. For example, the Federal Circuit did not consider the following facts, which eviscerate this key assumption and show that an "ANDA exception" is not warranted.

First, ANDAs are frequently withdrawn. *See* FDA Statistics (reporting 233 withdrawals from October 2015 through August 2016; 170 withdrawals in FY 2015; 179 withdrawals in FY 2014; 107 withdrawals in FY 2013).[6] When an ANDA is withdrawn, the generic product subject of that ANDA will never be marketed.

Second, the FDA may not approve the ANDA as a result of various deficiencies. For example, the FDA revoked tentative approval for Ranbaxy's generic versions of esomeprazole (Nexium) and valganciclovir (Valcyte).[7] And Ranbaxy failed to obtain FDA approval to market tamsulosin hydrochloride (Flomax), despite having reached a patent settlement agreement allowing it to launch that drug.[8]

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6. www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm (last visited Oct. 20, 2016) (previous years are available through links at the bottom of the page).

7. *See* CNBC, *US Pulls Approval for Ranbaxy copies of AstraZeneca and Roche drugs*, *available at* http://www.cnbc.com/2014/11/06/us-fda-ranbaxy-cant-produce-generic-versions-of-nexium-and-valcyte-dj.html (last visited Oct. 20, 2016).

8. Rumman Ahmed, Ranbaxy Fails to Launch Generic Flomax, http://www.wsj.com/articles/SB10001424052748703862704575098820612090224 (last visited Oct. 20, 2016).

Third, the FDA will not approve an ANDA if the reference branded drug is removed from the market for safety or efficacy reasons. *See* 21 U.S.C. § 355(j)(6). For example, the FDA blocked all ANDAs seeking to sell the original version of oxycodone (OxyContin®) in favor of a new patented abuse-resistant version. *See* FDA, FDA approves abuse-deterrent labeling for reformulated OxyContin, (Apr. 16, 2013) www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm (last visited Oct. 20, 2016) ("Agency will not approve generics to original OxyContin."); FDA Determination that the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273 (Apr. 18, 2013); Eric Palmer, Fierce Pharma, FDA Halts generic OxyContin, handing Purdue a victory, www.fiercepharma.com/regulatory/fda-halts-generic-oxycontin-handing-purdue-a-victory (last visited Oct. 20, 2016) ("Today as Purdue Pharma's patent for the original OxyContin expired, the FDA came down on their side, saying 'the benefits of original OxyContin no longer outweigh its risks' and banned any copies from approval."). Nor is this a rare occurrence. *See, e.g.*, Ondansetron (Ondansetron Hydrochloride) Injection, 80 Fed. Reg. 32,962 (June 10, 2015); Chloromycetin® (Chloramphenicol), 77 Fed. Reg. 41,412 (July 13, 2012); Halflytely® and Bisacodyl Tablets Bowel Prep Kit, 76 Fed. Reg. 51,037 (Aug. 17, 2011) & 75 Fed. Reg. 13,292 (Mar. 19, 2010); Albamycin® (Novobiocin Sodium), 76 Fed. Reg. 3,143 (Jan. 19, 2011); Brevibloc® (Esmolol Hydrochloride) Injection, 75 Fed. Reg. 24,710 (May 5, 2010); Cernevit®-12 (Multivitamins for Infusion), 75 Fed. Reg. 12,760 (Mar. 17, 2010).

Fourth, the ANDA filer may decide not to market the drug for business reasons or for numerous other reasons,

such as a decision to sell or transfer its right to market the drug, or as a result of a settlement. It is simply not true, then, that the mere filing of an ANDA indicates any "planned, non-speculative harmful conduct." App.13. The ANDA product may never reach the market. And if it does, it will likely only be after all allegations of infringement have been rejected.

C. The result of the Federal Circuit's novel "ANDA exception" is an undesirable concentration of ANDA cases in only two district courts.

As the Petition notes, ANDA cases have historically been concentrated in just a few district courts. *See* Pet. at 1. In fact, between 2009 and 2015, 73 percent of all ANDA suits were filed in either the District of Delaware or the District of New Jersey.[9] If the Federal Circuit had followed this Court's *Daimler* decision, this unwarranted concentration of cases would have corrected itself. Instead, the Federal Circuit's "ANDA exception" cements the status of the Delaware and New Jersey district courts as the unintended special ANDA courts.[10]

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9. Ryan Davis, *Mylan Ruling Cements Del., NJ As Top ANDA Venues*, http://www.law360.com/articles/774236/mylan-ruling-cements-del-nj-as-top-anda-venues (last visited Oct. 20, 2016) (reporting statistics on cases filed between 2009 and 2015) (citing data from Lex Machina); *see also* Brian C. Howard & Jason Maples, Lex Machina, Hatch-Waxman/ANDA Litigation Report 2015, at 3–4 (Apr. 2016).

10. Indeed, lawyers representing branded drug companies cite the expertise of the Delaware and New Jersey district courts as the reason branded companies overwhelmingly choose to file ANDA suits in those districts. *See id.*

There are compelling reasons to be skeptical of this concentration of ANDA litigation in just two courts. As an initial matter, the decision to create a specialist court requires complex balancing and should be left to Congress. *See, e.g.*, Administrative Conference of the United States, Recommendation 91-9, at 1 (Dec. 13, 1991), *available at* https://www.acus.gov/sites/default/files/documents/91-9.pdf (last visited Oct. 20, 2016) (recommending against a proposal to create specialized courts for review of all administrative law cases, recognizing that the creation of a specialist court requires "a complex balancing of various factors: the need for uniform law versus the benefits of 'percolation' in the decentralized circuits; the value of expert decision makers versus the broader perspective of generalists; the efficiency of specialization versus the risk of bias that specialization entails.").

As discussed above, Congress intended that ANDA cases should be subject to the existing multi-district litigation rules. *See* H.R. Rep. No. 98-857(I), at 28, *as reprinted in* 1984 U.S.C.C.A.N. at 2661. Thus, Congress emphatically did not intend for the Hatch-Waxman Act to create specialized "ANDA courts." Indeed, when Congress wants to establish specialized courts, it knows how. *See, e.g.*, 28 U.S.C. § 1491 (conferring jurisdiction on the Court of Federal Claims); 28 U.S.C. § 1581 (conferring jurisdiction on the Court of International Trade); 26 U.S.C. § 7441 (establishing the United States Tax Court); 28 U.S.C. § 1295 (conferring jurisdiction on the Court of Appeals for the Federal Circuit).

Moreover, as Seventh Circuit Chief Judge Diane Wood has explained, there are strong arguments against further specialization in the federal judiciary:

Nevertheless, powerful arguments against fundamentally changing the role of the Article III judge also exist. In my view, the strongest one relates to the accountability of the courts to the rest of society. Generalist judges cannot become technocrats; they cannot hide behind specialized vocabulary and "insider" concerns. The need to explain even the most complex area to the generalist judge (and often to a jury as well) forces the bar to demystify legal doctrine and to make the law comprehensible. This creates obvious benefits for clients as well as courts, since in today's skeptical world clients are not likely to warm to the "trust me, I know what is best for you" explanation either.

Related to this observation is the fact that the generalist judge is less likely to become the victim of regulatory capture than her specialized counterpart, despite the best of intentions on the latter's side. If one never emerges from the world of antitrust, to take one field that I know well, one can lose sight of the broader goals that lie behind this area of law; one can forget the ways in which it relates to other fields of law like business torts, breaches of contract, and consumer protection, and more broadly the way this law fits into the loose "industrial policy" of the United States. Economic mumbo-jumbo is already prevalent in the field, but lawyers talk of the trade-off between the deadweight loss "triangle" and the income transfer "rectangle" at their peril in front of a judge who does not live and breathe

> the field. Specialists need to emerge from their cocoons from time to time and find out how their smaller world fits in with the larger one. Today, nothing prevents those who would prefer an "expert" decisionmaker from choosing the arbitration route. Once the aid of the courts is invoked, however, the broader perspective should legitimately be part of the picture.

Diane P. Wood, Generalist Judges in A Specialized World, 50 S.M.U.L. Rev. 1755, 1767 (1997).

While there are certainly benefits to litigating cases before specialists, they are outweighed by the downsides here. When litigation is spread across the country, many different courts will confront the same or similar legal questions. If there is an obvious right answer, most of the courts will agree. But if the question is difficult, complex, or subtle, the courts will often arrive at differing answers. Each court to consider the question then has the benefit of the earlier courts' analyses. This natural process allows questions to percolate until either a consensus emerges or this Court's review is necessary to resolve the question.

Concentrating the large majority of ANDA litigation in two district courts arrests this vital process for the complex legal issues involving the Hatch-Waxman Act. This effect is compounded by the fact that all appeals in ANDA cases go to the Federal Circuit, so questions regarding the Hatch-Waxman Act do not benefit from the consideration of multiple Circuit Courts. *Cf.* Richard A. Posner, The Federal Courts: Challenge and Reform 257 (1996) ("[T]he Supreme Court will not have the benefit of competing judicial answers to choose among when

deciding questions within the domain of the specialized court, except when there is a dissenting opinion in that court.").

Without this Court's review, the concentration of ANDA cases in two districts will persist. In one of the cases below, the district court reasoned that while specific jurisdiction was historically disfavored in ANDA cases, that conclusion needed to be revisited in light of *Daimler's* dramatic restriction of the scope of general jurisdiction. *See AstraZeneca AB v. Mylan Pharms., Inc.*, 72 F. Supp. 3d 549, 557 (D. Del. 2014) ("The court notes that specific jurisdiction has historically been disfavored by courts as a basis to exercise jurisdiction over generic drug company defendants in ANDA cases. The court finds it necessary, however, to look closely at AstraZeneca's argument now that the standard for general jurisdiction—the typical avenue for bringing ANDA cases—has changed.") (citations omitted), *aff'd*, 817 F.3d 755 (Fed. Cir. 2016). But personal jurisdiction is not a sliding scale, where the narrowed scope of general jurisdiction is inevitably replaced by a corresponding expansion of specific jurisdiction, ensuring the bottom line result that every ANDA defendant is subject to jurisdiction in Delaware and New Jersey based solely on the submission of an ANDA to the FDA.

CONCLUSION

For the reasons set forth herein and in the Petition, amicus curiae GPhA respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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