No. A-___

IN THE SUPREME COURT OF THE UNITED STATES

PFIZER INC.,

Applicant-Petitioner,

v.

APOTEX, INC. (FORMERLY KNOWN AS TORPHARM, INC.)

Respondent,

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

---

MOTION TO EXPEDITE CONSIDERATION OF PFIZER'S PETITION FOR WRIT OF CERTIORARI SEEKING A GVR ORDER IN LIGHT OF *KSR v. TELEFLEX*, 550 U.S. ___, 127 S. Ct. 1727 (April 30, 2007)

DOUGLAS R. COLE
JONES DAY
325 John H. McConnell Blvd., Suite 600
Columbus, OH 43216
(614) 469-3939

RICHARD G. GRECO
MILTON SHERMAN
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000

GLEN D. NAGER
(*Counsel of Record*)
GREGORY A. CASTANIAS
MICHAEL S. FRIED
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

Counsel for Applicant-Petitioner

Petitioner Pfizer Inc., respectfully requests that the Court expedite its consideration of the petition Pfizer filed in this case seeking a GVR of the Federal Circuit's decision below in light of the Court's intervening decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (April 30, 2007). Just one week ago, on May 21, 2007, the Federal Circuit denied Pfizer's petition for rehearing *en banc*, over vigorous dissents from three circuit judges, in a case that imposes severe financial repercussions on Pfizer, and more importantly, has potentially wide-reaching consequences for the entire pharmaceutical research industry (as explained by the dissenters from the denial of rehearing *en banc* in the Federal Circuit, and evidenced by the *amici curiae* who filed briefs in support of the rehearing petition there). *See Pfizer Inc. v. Apotex, Inc.*, No. 2006-1261, 2007 U.S. App. LEXIS 11886, at *3 (Fed. Cir. May 21, 2007). In particular, in the course of invalidating claims 1-3 of Pfizer's U.S. Patent No. 4,879,303 ("the '303 patent"), the Federal Circuit adopted an untenable view of obviousness in the pharmaceutical research context that, in the words of Judge Rader, "calls into question countless pharmaceutical patents, which in turn could have a profoundly negative effect on investments into the design and development of new life-saving pharmaceuticals." *Id.* at *21 (Rader, J., dissenting).

In ordinary circumstances, Pfizer would seek review of these "questions of exceptional importance," *id.* at *13 (Lourie, J., dissenting), under the normal timeframe for such review. The circumstances here, however, are far from ordinary. Pfizer's '303 patent expired on March 25, 2007, and the only rights it has remaining—rights of pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(A)-(B)—will expire on September 25, 2007. As more fully explained in Pfizer's

petition for writ of certiorari and its application to recall the mandate, both of which are being filed concurrently with this motion, more urgent review in this case is necessary.

In brief, Pfizer is the assignee of the '303 patent. That patent covers amlodipine besylate, the active ingredient in Pfizer's Norvasc®, the largest selling brand-name cardiovascular drug in the world.

In 2003, Apotex filed an Abbreviated New Drug Application claiming that Pfizer's '303 patent was invalid and unenforceable and seeking FDA approval to sell generic amlodipine besylate. Pfizer reponded by suing Apotex for infringement. *See Pfizer Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007). *See also* 35 U.S.C. § 271(e)(2)(A) (making it an "act of infringement" to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent"). Although Apotex conceded that its product would infringe the '303 patent, it contended that the patent was invalid on obviousness grounds and unenforceable due to Pfizer's alleged inequitable conduct in connection with the prosecution of the '303 patent. *Id.* The district court disagreed, finding Pfizer's patent to be both valid and enforceable.

Apotex appealed. On March 22, 2007, a three-judge panel of the Federal Circuit (with one judge concurring in the judgment only) reversed the district court, finding that claims 1-3 of Pfizer's '303 patent were obvious as a matter of law. In doing so, the Federal Circuit adopted a distorted view of obviousness that has severe implications for the entire pharmaceutical industry. Accordingly, Pfizer, with support from industry groups, sought rehearing *en banc*. While that petition was pending, on April 30, 2007, this Court issued its decision in *KSR Int'l Corp. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (April 30, 2007), in which it made important clarifications to the analytical framework governing the obviousness analysis, and Pfizer advised the Federal Circuit of that decision pursuant to Rule 28(j) of the Federal Rules of Appellate

Procedure. On May 21, 2007, however, the Federal Circuit denied rehearing *en banc* with no attempt to reconcile its decision with *KSR*, and it ordered its mandate to issue immediately.

Three judges dissented, citing both the exceptional importance of the issues presented, and the dire consequences to the pharmaceutical industry of the analytical obviousness framework that the panel had adopted. In particular, these judges warned that "the ruling in this case has important policy as well as legal implications," *Pfizer Inc.*, 2007 U.S. App. LEXIS 11886, at *5 (Newman, J., dissenting); that "diminished access to patenting will affect the kind and direction of product development," *id.* at *7, and, perhaps most importantly, that "this decision calls into question countless pharmaceutical patents, which in turn could have a profoundly negative effect on investments into the design and development of new life-saving pharmaceuticals." *Id.* at *21 (Rader, J., dissenting).

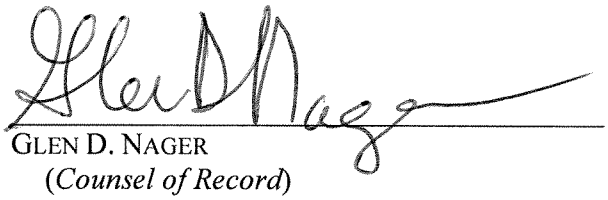
Now, however, unless the Court grants this motion to expedite, events may conspire to deprive the Court of the opportunity to require the court below to reconcile its obviousness analysis with the Court's instructions in *KSR*. Pfizer's '303 patent expired on March 25, 2007. This case remains viable only because Pfizer is entitled to an additional six months of exclusivity under the Better Pharmaceuticals for Children Act, but even that period expires on September 25, 2007, before the Court would likely act on Pfizer's petition in the normal course. Thus, as more fully explained in that petition, unless the Court expedites its consideration of Pfizer's GVR request, the case will become moot before the Court can act.

Moreover, solely as a result of that passage of that time, Pfizer will also have been irrevocably deprived its right to that remaining exclusivity period, with severe ramifications for the company and its shareholders. Indeed, Pfizer estimates that the remaining exclusivity period is worth over $500 million.

The Court has previously agreed to expedite consideration of petitions where that was the necessary to allow the Court to consider a matter of exceptional importance that was also exceptionally time-sensitive. *See, e.g.*, *Chisom v. Roemer*, 498 U.S. 1060 (1991) (expedited consideration in Voting Rights Act case); *AT&T Corp. v. Iowa Utils. Bd.*, 522 U.S. 1043 (1998) (granting motion to expedite in case involving interpretation of Telecommunications Act that had significant ramifications for telephone industry). Both those attributes are present here. The court below adopted an obviousness analysis that will have sweeping implications for the pharmaceutical industry and those who rely on its products, and it has done so without availing itself of the opportunity to ensure that its decision comports with the Court's latest guidance on that issue. And if the Court declines to expedite review of the petition, the mere passage of time could saddle the industry with the ongoing effects of that decision. Moreover, the relief that Pfizer seeks in its petition, a summary GVR order rather than a full review on the merits, is particularly susceptible to treatment in an expedited fashion.

Accordingly, Pfizer respectfully urges the Court (1) to require Apotex to respond to Pfizer's petition no later than 3:00 p.m. Eastern Standard Time (EST) on June 14, 2007, (2) to require Pfizer to reply no later than 3:00 p.m. Eastern Standard Time (EST) on June 16, 2007, and (3) to determine whether to grant the requested GVR order before the end of this Term.

Respectfully submitted,



GLEN D. NAGER
(Counsel of Record)
GREGORY A. CASTANIAS
MICHAEL S. FRIED
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

Counsel for Applicant-Petitioner

DOUGLAS R. COLE
JONES DAY
325 John H. McConnell
Blvd., Suite 600
Columbus, OH 43216
(614) 469-3939

RICHARD G. GRECO
MILTON SHERMAN
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000