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

APPLICATION TO RECALL THE MANDATE AND STAY THE CASE PENDING DISPOSITION OF PETITION FOR WRIT OF CERTIORARI

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To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit.

On March 22, 2007, a panel of the United States Court of Appeals for the Federal Circuit (with one judge concurring in the result only) reversed a judgment of the United States District Court for the Northern District of Illinois, entered on findings made after a bench trial, and held—based on an application of the Federal Circuit's then-existing version of its "teaching-suggestion-motivation test"—that claims 1-3 of Pfizer's U.S. Patent No. 4,879,303 ("the '303 patent") were invalid as a matter of law for obviousness. The '303 patent covers amlodipine besylate, the active ingredient in Pfizer's anti-hypertensive drug Norvasc®, the most prescribed brand-name high-blood-pressure medicine in the world, and one that earns Pfizer more than $150 million in revenues per month.

While Pfizer's petition for rehearing *en banc* was pending, this Court, on April 30, 2007, decided *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007), in which the Court altered the Federal Circuit's established framework for determining obviousness. Pfizer filed a Fed. R. App. P. 28(j) letter alerting the court below to the new decision and its relevance here.

On May 1, 2007, Apotex also filed a motion in which it sought both expedited denial of the petition for rehearing *en banc* and expedited issuance of the mandate. *See* Ex. A. Pfizer responded to that motion explaining again why *en banc* rehearing was vital and appropriate in this case. *See* Ex. B.

On May 21, 2007, however, the Federal Circuit, over vigorous dissents from Circuit Judges Newman, Lourie, and Rader, denied rehearing *en banc*. *See Pfizer Inc. v. Apotex, Inc.*, No. 2006-1261, 2007 U.S. App. LEXIS 11886, at *3 (Fed. Cir. May 21, 2007), attached as Ex. C. It did so despite the fact that, as the dissenting judges recognized, the decision "presents questions of exceptional importance," *id*. at *13 (Lourie, J.), and "changes the criteria as well as the analysis of patentability, with results of particular significance for their effect on the conduct of R&D, the costs

of drug development, and the balance between generic access to established products and the incentives [for] development of new products," *id*. at *7 (Newman, J.). Equally important, the *en banc* court also below ruled that Apotex's "motion for expedited issuance of the mandate is granted," and the mandate issued that day. *See id*. at *3.

As a result of these twin rulings, this case of "exceptional importance" (as also reflected by the many *amici* that filed briefs filed on both sides at the *en banc* stage such as SmithKline Beecham Corp., the Biotechnology Industry Organization, the Pharmaceutical Research and Manufacturers of America, and the Generic Pharmaceutical Association) was decided under the now-outdated, pre-*KSR* obviousness standards, making the need for a GVR order plain. Thus, concurrently with this application to recall the mandate, Pfizer is filing a petition for certiorari seeking a GVR order from the Court.

Absent the Court's action on this application, however, that petition alone cannot ameliorate the dire consequences that will flow from the Federal Circuit's decision. Pfizer's '303 patent reached the end of its term and expired on March 25, 2007. In exchange for conducting tests to determine the efficacy of amlodipine besylate in children, however, Pfizer received an additional six-month period of exclusivity (the so-called "pediatric exclusivity period") under the Best Pharmaceuticals for Children Act. *See* 21 U.S.C. § 355a. Accordingly, Pfizer has the right to manufacture and distribute amlodipine besylate without additional competition through September 25, 2007, some four months from now.[1] Under the FDA's interpretation of the controlling statutes, however, the pediatric exclusivity period ends immediately upon the issuance of the mandate from the Federal Circuit invalidating the patent. *See Mylan Labs. v. Leavitt*, ___ F. Supp. 2d ___, 2007 WL 1241884 (D.D.C.

[1] The exclusivity provision basically prevents the FDA from approving abbreviated new drug applications ("ANDAs") regarding amlodipine besylate for six months following the expiration of the '303 patent. One competing manufacturer, Mylan, had already received approval of its ANDA even prior to the expiration of the patent. Because it already had an approved ANDA, Mylan was permitted by FDA to begin making and selling generic amlodipine besylate without regard to the additional period of pediatric exclusivity.

April 30, 2007). Apotex has taken full advantage of that, launching its generic version of amlodipine besylate on May 24, 2007. Thus, absent a recall of the mandate from this Court, generic manufacturers need only to successfully assert the preclusive effect of the decision below and gain FDA approval of their abbreviated new drug applications ("ANDAs") to begin distributing amlodipine besylate, which will deprive Pfizer of the remaining exclusivity period to which it is entitled.

Accordingly, Pfizer now respectfully requests, pursuant to Supreme Court Rule 23.1 and 28 U.S.C. § 2101(f), that the Court recall and stay the Federal Circuit's mandate while Pfizer's petition for certiorari seeking a GVR order is pending. (Pfizer has also sought, in a separately filed motion, expedited briefing on that petition.) As the *en banc* court below already expressly determined that the mandate would issue immediately and entered an order to that effect, *see* Ex. C at *3, Pfizer presents its request for relief here. *See* Supreme Court Rule 23.3.

Pfizer readily acknowledges that it is seeking extraordinary relief, and it does not make this request lightly. But the record here compellingly shows why such relief is necessary. As more fully described below, each of the four factors on which the Court relies in considering such requests is clearly present here. *See Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers). **First**, there is a "reasonable probability" that the Court will grant certiorari and, **second**, a "fair prospect" that it will at least vacate the decision below. As noted above, given the panel's failure to consider *KSR*, a GVR order is clearly warranted. **Third**, Pfizer will suffer irreparable harm if the stay is denied. Issuance of the mandate essentially opens the door for Pfizer's competitors to begin releasing competing products, thereby depriving Pfizer of its remaining statutorily-guaranteed exclusivity period. **Fourth**, the balance of equities overwhelmingly favors Pfizer. Recalling the mandate means only a slight delay to provide the Court the opportunity to consider whether the decision below warrants future consideration in light of *KSR*, a delay which could be minimized even

further if the Court orders expedited briefing on that petition. Failing to recall the mandate, however, imposes a serious risk of immediate and irreversible harm on Pfizer's operations and its shareholders.

Given the important ramifications of the obviousness issues that this case presents, the case should be decided with the benefit of this Court's most recent guidance, and only a recall of the mandate will accomplish that objective.

STATEMENT OF THE CASE

As more fully explained in Pfizer's concurrently-filed petition for certiorari, Pfizer is the assignee of the '303 patent, which covers amlodipine besylate. Pfizer commercially sells amlodipine besylate in the United States as Norvasc®, a drug that the FDA has approved for the treatment of hypertension and vasopastic angina. *See Pfizer Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1352 (Fed. Cir. 2007). In 2003, Apotex, the defendant below, filed an ANDA with the FDA seeking approval to commercially sell amlodipine besylate tablets before Pfizer's '303 patent expired. Apotex certified in its ANDA that it believed the '303 patent was invalid and unenforceable. Pfizer responded to the ANDA by filing suit against Apotex on July 30, 2003 in the United States District Court for the Northern District of Illinois claiming patent infringement. *See id. 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").

Apotex conceded that if the patent was valid and enforceable, the drug it proposed to manufacture in its ANDA would infringe the '303 patent. *See Pfizer Inc.*, 480 F.3d at 1352. Apotex contended, however, that the patent was invalid on obviousness grounds and that the patent was unenforceable due to Pfizer's alleged inequitable conduct in connection with the prosecution of the '303 patent. *Id*.

With regard to obviousness, the parties both acknowledged that an earlier Pfizer patent had disclosed amlodipine maleate, a chemical compound with identical therapeutic benefits, but one that

was hard to formulate in tablet form due to its chemical instability and its stickiness (*i.e.*, the compound stuck to the processing equipment during manufacture). *Id*. at 1353–54. Pfizer researchers discovered amlodipine besylate as a result of experiments they undertook to identify a compound that would overcome these manufacturing problems while maintaining the therapeutic qualities of amlodipine maleate.

Apotex argued in the trial court that the earlier patent that had disclosed the maleate salt of amlodipine (*i.e.*, amlodipine maleate), combined with two other references that disclosed the use of besylate salt as a suitable pharmaceutical salt (albeit one that had been used in less than .25% (*i.e.*, one in 400) of the drugs for which FDA approval had been sought), rendered obvious the invention claimed in the '303 patent. After a bench trial, however, the district court rejected that argument, finding that one of ordinary skill in the art would not have had an "expectation of success" in combining besylate with amlodipine because "[t]here is no reliable way of predicting the influence of a particular salt species on the behavior of a parent compound," and that amlodipine besylate was "unexpectedly superior" to the amlodipine maleate claimed in the prior art. *Id*. at 1357. It therefore upheld the patent against a claim of obviousness, the same conclusion that two other district court judges have reached in currently pending challenges to the '303 patent by other manufacturers. *See Pfizer Inc. v. Mylan Labs., Inc.*, No. 02:02CV1628, 2007 WL 654274 (W.D. Pa. Feb. 27, 2007), *appeal docketed*, No. 2007-1194 (Fed. Cir. Mar. 6, 2007); *Pfizer Inc. v. Synthon Holdings BV*, No. 1:05CV39, 2006 WL 2553370 (M.D.N.C. Aug. 31, 2006), *appeal docketed*, No. 2007-1045 (Fed. Cir. Nov. 9, 2006).

The Federal Circuit, in an opinion issued on March 22, 2007—five weeks before the Court's April 30, 2007 decision in *KSR*—reversed, finding that the claimed invention was obvious as a matter of law. 480 F.3d at 1352–53. In reaching that result, the court relied on a version of its "'teaching, suggestion, or motivation' test (TSM test)," which has been criticized by this Court. *See*

KSR, 127 S. Ct. at 1741-42 (rejecting Federal Circuit's rigid reliance on TSM test). In particular, the lower court said that the invention was obvious if Apotex showed "by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer Inc.*, 480 F.3d at 1361. Moreover, it adopted an understanding of "reasonable expectation of success" under which an invention would not be patentable any time that it resulted from trial and error testing, a result that, as one of the dissenting judges in the denial of rehearing *en banc* complained, is particularly troubling in the pharmaceutical area where "[m]any if not most pharmaceutical inventions are discovered though a routine screening protocol or through an established trial and error process." *Pfizer Inc.*, 2007 U.S. App. LEXIS 11886, at *21 (Lourie, J., dissenting from denial of rehearing *en banc*).

Given the problematic understanding of "obviousness" that the panel decision adopted, along with the dire consequences that standard would have for pharmaceutical research generally, on April 5, 2007, Pfizer filed a petition seeking rehearing *en banc*. While that petition was pending, this Court issued its decision in *KSR*. Two days later, Pfizer filed a letter under Fed. R. App. P. 28(j) in the Federal Circuit alerting the court to the new decision and explaining its relevance.

On May 21, 2007, over the dissent of three judges, the court denied the petition for rehearing *en banc*, without explanation, and with no reference to the Court's *KSR* opinion. It did so despite the fact that, as the dissenting judges noted, "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 "the panel decision changes the criteria as well as the analysis of patentability," *id*. at *8; that "diminished access to patenting will affect the kind and direction of product development," *id*. at *7; and that the case "presents questions of exceptional importance," *id*. at *13 (Lourie, J., dissenting). Perhaps most importantly, it neglected to rehear the case notwithstanding that, in the words of Judge Rader's

dissent, "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).

The court also ordered the mandate to issue immediately, meaning that Apotex was able to launch its competing generic product on May 24, 2007, and others are now free to assert the preclusive effect of the decision below and seek FDA approval of their ANDAs, which will further flood the market with generic versions of Norvasc®.

ARGUMENT

A well-established four-part test governs the grant of a stay application pending disposition of a petition for a writ of certiorari:

> First, it must be established that there is a "reasonable probability" that four Justices will consider the issue sufficiently meritorious to grant certiorari or to note probable jurisdiction. Second, the applicant must persuade [the Justice] that there is a fair prospect that a majority of the Court will conclude that the decision below was erroneous . . . . Third, there must be a demonstration that irreparable harm is likely to result from the denial of a stay. And fourth, in a close case it may be appropriate to "balance the equities"—to explore the relative harms to applicant and respondent, as well as the interests of the public at large.

Rostker v. Goldberg, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers) (citing *Whalen v. Roe*, 423 U.S. 1313, 1316-17 (1975) (Marshall, J., in chambers)) (internal citations omitted); *accord Packwood v. Senate Select Comm. on Ethics*, 510 U.S. 1319, 1320–21 (1994) (Rehnquist, C.J., in chambers). This stay application satisfies all four criteria.

I. THE QUESTION PRESENTED IN THIS CASE IS SUBSTANTIAL AND SUFFICIENTLY MERITORIOUS TO WARRANT CERTIORARI, AND THE COURT WILL LIKELY CONCLUDE THAT THE DECISION BELOW SHOULD BE VACATED AND THE CASE REMANDED FOR FURTHER CONSIDERATION IN LIGHT OF *KSR*.

Where, as here, the petition will not seek to have the Court review the decision on the merits, but rather to have the decision vacated and remanded for further consideration in light of intervening

developments, the first two factors essentially collapse into one question: Is there a reasonable probability that the Court will grant the petition, vacate the judgment below, and remand for further consideration in light of that intervening development ("GVR")? The answer to that question here is "yes."

A. The Court has held that GVRs are appropriate where, as here, an intervening change in Supreme Court case law has a "reasonable probability" of affecting the determination below.

As more fully explained in the petition for certiorari, the GVR order is an "integral part of this Court's practice," appropriate "[w]here intervening developments, or recent developments that [the Court has] reason to believe the court below did not fully consider, reveal a reasonable probability that the decision below rests on a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation." *Lawrence v. Chater*, 516 U.S. 163, 166, 167 (1996). That perfectly describes the situation here. The court below invalidated Pfizer's patent on obviousness grounds, but five weeks later, while the petition for rehearing *en banc* was still pending, this Court's *KSR* decision altered the obviousness landscape in ways directly relevant to the decision below.

1. Although Apotex claimed that the patent was both invalid as a result of obviousness and unenforceable based on inequitable conduct, the sole issue the court below reached in denying Pfizer relief was the former: "From our *de novo* assessment of the determination below on obviousness . . . we conclude that the district court erred in holding that the claims of the '303 patent would not have been obvious." *Pfizer Inc.*, 480 F.3d at 1372. And, in reaching that determination, the court relied on the obviousness test from *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006), under which "the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine

the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer Inc.*, 480 F.3d at 1361. Later portions of the opinion confirmed that the court's reference to "motivation" was a shorthand for the Circuit's teaching, suggestion, motivation ("TSM") test. Indeed, the decision expressly noted that the "suggestion, teaching or motivation to combine the relevant prior art teachings" does not "have to be found explicitly in the prior art references sought to be combined, but rather 'may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself.'" *Id*. at 1362 (citation omitted). *See also id*. at 1364 (court concluding that one skilled in the art "would have been motivated to combine the teachings [of the prior art] to produce the besylate salt of amlodipine").

With regard to the other factor from *DyStar*, whether one skilled in the art would have had a "reasonable expectation of success" in using besylate rather than maleate to combine with the amlodipine, the court found that element present, notwithstanding that Pfizer's expert witness had testified at trial without contradiction that "one of ordinary skill in the art could neither draw any conclusions nor have any expectations about the properties of amlodipine besylate from the properties of a besylate salt or a different compound." *Pfizer Inc.*, 2007 U.S. App. LEXIS 11886, at *6 (Newman, J., dissenting from denial of rehearing *en banc*). Indeed, the trial court had found as a matter of fact that "the besylate salt clearly and unexpectedly exhibited a superior combination of properties when compared to what was suggested in the preferred preparation." *Id*. at *13 (Lourie, J., dissenting from denial of rehearing *en banc*) (citing district court ruling). The appellate court rejected the clear implication of that finding, however, essentially holding that "the invention was the result of routine experimentation, and therefore was not patentable," making the patentability decision turn on the manner of discovery, in direct contravention of 35 U.S.C. § 103, and precluding the patentability

of discoveries made by trial-and-error testing, notwithstanding that the results of that testing may have been surprising or unexpected.

2. The Court's decision in *KSR*, issued five weeks after the panel decision below, changed the obviousness analysis in at least two ways directly relevant here. First, *KSR* expressly rejected the rigid application of the TSM test as the basic test for obviousness. According to the Court, "[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation." 127 S. Ct. at 1741. Second, the Court in *KSR* reaffirmed the notion that where combinations yield unexpected results, the unexpected nature of the results cuts against a finding of obviousness. To be sure, if "pursu[ing] the known options" leads to "anticipated success," it is likely a claimed invention is "the product not of innovation but of ordinary skill and common sense." *Id*. at 1742. *See also id*. at 1738 (combination is obvious "when it does no more than yield predictable results"). But, the Court also noted that where the combined elements work together in an "unexpected and fruitful manner," that supports a finding of nonobviousness. *Id*. at 1740. These two aspects of this Court's decision in *KSR* reveal that the court below used a flawed analytical framework, creating at least a "reasonable probability" that the court may come out differently after giving a full and proper consideration to *KSR*.

Further confirming the need for more analysis in light of *KSR*, the *KSR* opinion expressly discussed the *DyStar* obviousness formulation that the court below relied on here. The Court noted that in *DyStar* the Federal Circuit had "elaborated a broader conception of the TSM test," but the Court declined to rule on whether that standard met *KSR*'s demands, saying only that that "is a matter for the Court of Appeals to consider in its future cases." 127 S. Ct. at 1743. That consideration needs to happen here in order to correctly decide the issues of "exceptional importance" presented by this case.

In short, *KSR* altered the analytical approach to obviousness, and the now-suspect pre-*KSR* obviousness analytical framework was the *sole* underpinning to the Federal Circuit's refusal to protect Pfizer's rights under the '303 patent, making a GVR both appropriate and necessary.

II. THE EQUITIES HERE STRONGLY CUT IN FAVOR OF RECALLING THE MANDATE AND STAYING FURTHER PROCEEDINGS IN THIS CASE PENDING DISPOSITION ON THE PETITION FOR CERTIORARI.

The Court's three-prong inquiry governing GVR practice, *see Chater*, 516 U.S. at 166, and its four-prong inquiry for stays pending certiorari, *see Rostker*, 448 U.S. at 1308, include consideration of the relative equities. Here, those equities point strongly in favor of granting Pfizer relief both on this application and on its concurrently-filed petition for certiorari. What the judges who dissented from the denial of rehearing referred to as the "exceptional importance" of the issues at stake here confirms the need for the Federal Circuit to take a new look at this case in light of *KSR*, and only through recalling the mandate can Pfizer receive the protection to which it is entitled pending that reconsideration.

1. While the issues at stake here are far more than merely financial, the immediate financial impact of the decision alone compels close attention. But for the decision below, Pfizer would have been entitled to an additional six months of pediatric exclusivity, which would have produced revenues of approximately $1.2 billion. As a result of the decision below, however, two generic competitors have launched (so far), forcing Pfizer to lose significant market share and pricing value and reducing its expected revenues during the remaining four months of the pediatric exclusivity term from an initial $800 million to, presently, not more than $200 million.

Recalling the mandate is the key element in avoiding that harm. The statute makes the date on which "the court determines" the validity of the patent the key date for the exclusivity provision. The FDA has interpreted this language to mean the date on which the Federal Circuit issues its mandate making a judgment of invalidity effective. *See Mylan Labs. v. Leavitt*, ___ F. Supp. 2d ___,

2007 WL 1241884 (D.D.C. April 30, 2007). Thus, until the mandate is recalled, competitors are free to assert the preclusive effect of the decision below and then seek approval of their ANDAs so that they can flood the market with generic equivalents.

2. Perhaps even more important than the impact on Pfizer, however, is the impact that the decision below will have on the pharmaceutical industry generally. As SmithKline Beecham noted in its *amicus curiae* brief in support of rehearing *en banc* in the Federal Circuit, the panel decision here "has broad ramifications that cast a cloud over countless patents." In the words of the BioTechnology Industry Association, also *amicus curiae* below, the standard for obviousness adopted here "would obviate a large percentage of goal-oriented biotechnology research." Indeed, even the panel rendering the decision here recognized that "the pharmaceutical industry may be particularly adversely impacted by application of" the standard it adopted here. *Pfizer Inc.*, 480 F.3d at 1367.

In language even more blunt, one of the judges dissenting from denial of rehearing *en banc* cautioned that "the panel decision changes the criteria as well as the analysis of patentability, with results of particular significance for the effect on the conduct of R&D, the costs of drug development, and the balance between generic access to established products and the incentive [for] development of new products." *Pfizer Inc.*, 2007 U.S. App. LEXIS 11886, at *7 (Newman, J., dissenting). Those changes have real-world consequences. As Judge Rader warned, the "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). Before the Federal Circuit implements an obviousness regime with such dramatic consequences not only for pharmaceutical companies, but also for those whose lives depend on the products pharmaceutical companies invent, that court should at least ensure that the rule it adopts is consistent with the Court's recent pronouncement on that subject.

The Federal Circuit's decision acknowledged that "obviousness is a complicated subject requiring sophisticated analysis" that requires "careful reading of the full text of a group of related precedents for all they say that is dispositive and for what they hold." Moreover, "[w]hen parties do not engage in . . . careful, candid, and complete legal analysis, much confusion about the law arises." Ironically, the Federal Circuit failed to heed its own admonition, by not giving this case a "careful, candid, and complete analysis" including this Court's *KSR* decision. Pfizer respectfully urges the Court to recall the mandate (and ultimately to grant, vacate and remand the decision below) to provide the lower court the opportunity to undertake that "careful, candid and complete legal analysis," one that includes a "careful reading" and consideration of this Court's decision in *KSR*, to avoid both the "confusion" that will otherwise result and the real-life consequences that will follow from that confusion both for the pharmaceutical industry and for those who rely on the products that that industry creates.

Respectfully submitted,

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