No. 06-____

IN THE

Supreme Court of the United States

PFIZER INC.,

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Prior to this Court's April 30, 2007 decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007), the Court of Appeals for the Federal Circuit applied its then-existing version of the "teaching-suggestion-motivation" test for obviousness in this case and, despite district court findings that there would be no expectation of success in combining the two elements that resulted in the patented invention and that the combination was "unexpectedly superior" to the prior art, reversed the district court and found claims 1-3 of Pfizer's U.S. Patent No. 4,879,303 ("the '303 patent") to be obvious as a matter of law. This Court rendered its *KSR* decision while Pfizer's petition for rehearing was pending in the Federal Circuit, yet, despite both the substantial doubt that *KSR* cast upon that court's teaching-suggestion-motivation test and the fact that *KSR* reinforced the role that unexpected results can play in showing nonobviousness, the Federal Circuit failed to rehear or give any reconsideration to the case in light of that intervening development in the law. Three judges dissented from the denial of rehearing *en banc*.

The questions presented are:

1. Whether the Federal Circuit's failure to reconsider its judgment under the *KSR* standard merits summarily granting the petition, vacating the judgment, and remanding for further consideration in view of *KSR*?

2. Whether, if the petition is not granted prior to September 25, 2007—when Pfizer's pediatric exclusivity for Norvasc® comes to an end—the Court should instead grant the petition and order the Court of Appeals' judgment vacated under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994).

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

The parties before this Court are petitioner Pfizer Inc. and respondent Apotex, Inc. (formerly known as TorPharm, Inc.).

There is no parent company or publicly held company owning more than 10% of petitioner's stock.

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PETITION FOR A WRIT OF CERTIORARI

Pfizer Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the United States District Court for the Northern District of Illinois was issued on January 17, 2006, and is unreported (App. 52a-68a).*

The panel opinion of the United States Court of Appeals for the Federal Circuit was issued on March 22, 2007, and is reported at 480 F.3d 1348 (App. 1a-38a). The Federal Circuit's order denying rehearing and rehearing *en banc*, over the dissents of three judges, is not yet reported; it can be found at 2007 U.S. App. LEXIS 11886 (App. 39a-51a).

JURISDICTION

The opinion of the United States Court of Appeals for the Federal Circuit was issued on March 22, 2007. App. 1a-38a. The Court of Appeals' order denying Pfizer's petition for rehearing *en banc* was issued on May 21, 2007. App. 39a-40a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Section 103(a) of Title 35, United States Code, provides:

> 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

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* Two other district courts have also upheld claims 1-3 of the patent at issue here against obviousness challenges, based upon extensive findings of fact. *See Pfizer Inc. v. Mylan Labs., Inc.*, No. 02:02CV1628, 2007 WL 654274 (W.D. Pa. Feb. 27, 2007); *Pfizer Inc. v. Synthon Holdings BV*, No. 1:05CV39, 2006 WL 2553370 (M.D.N.C. Aug. 31, 2006).

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.

STATEMENT

1. Pfizer is the assignee of U.S. Patent No. 4,879,303 ("the '303 patent") (Patent App. Tab 1), which covers amlodipine besylate. Amlodipine besylate is the active ingredient in Norvasc®, which is the world's largest selling brand-name drug for treating hypertension.

Pfizer scientists invented the compound amlodipine in 1981, and first sought to develop it as a cardiovascular drug in the form of amlodipine's maleate salt (amlodipine maleate). In an effort to create a commercially viable tablet form of amlodipine maleate, Pfizer scientists ran into two problems: One, amlodipine maleate was unstable, meaning that it produced numerous degradation products; two, it was too sticky, which meant that it adhered to tablet-making machinery and made mass production extraordinarily difficult. App. 3a-5a.

As the district court found, "[t]his was no small problem." App. 54a. Attempts to work around these problems by changing the excipients (the inactive substances used as the carrier of the drug) in the dosage form were unsuccessful. Two years into the project, with clinical trials well under way, the problems were so serious that the Pfizer scientist leading the project was seriously considering abandoning amlodipine entirely in favor of another candidate. Before abandoning the project entirely, however, the Pfizer scientists determined to try reacting amlodipine with other acids in order to create different salts of amlodipine. App. 54a. There was no basis to know if this would be successful, however, as the physicochemical properties of a new salt are entirely unpredictable. C.A. App. 884.

Pfizer scientists created a number of different salts and tested their properties. Amlodipine besylate, which was the reaction product of amlodipine and benzene sulphonic acid, resolved the instability and stickiness problems, but still maintained the good properties of amlodipine maleate (solubility and nonhygroscopicity—meaning a substance's tendency to attract and absorb moisture from the atmosphere). Amlodipine besylate was the only new salt that solved the problems of the prior art without introducing any new problems. App. 6a. As the district court found, "[t]his was no small task . . . many organic acids will not [produce an acceptable salt]. Some will only form oils, some are unstable, some produce undesirable or dangerous byproducts." App. 56a.

In October 1984, the inventors (Dr. Wells and Mr. Davison) made the extraordinary recommendation that Pfizer switch the salt form in its proposed drug product, after most of the safety and efficacy trials in humans had been completed. Pfizer accepted the recommendation, which was one that no pharmaceutical company would accept unless faced with serious formulation problems. C.A. App. 862, 938.

In April 1986, Pfizer applied for a U.K. patent on amlodipine besylate, and a counterpart U.S. application followed shortly thereafter. App. 6a. The application issued as the '303 patent on November 7, 1989. App. 8a.

2. Prior to Pfizer's application for a patent covering amlodipine besylate, there was only one other salt of amlodipine disclosed in the prior art—amlodipine maleate—which was disclosed in U.S. Patent No. 4,572,909 ("the '909 patent") (Patent App. Tab 2), also assigned to Pfizer. Importantly, nowhere in the '909 patent is there any reference to the besylate salt, to benzene sulphonic acid, nor for that matter any other member of the sulphonic acid group. The '909 patent identifies 12 acid anions as potential candidates for making salts, but each has a very different

structure than the besylate anion. App. 17a-18a; C.A. App. 884-85, 7672.

Apotex's obviousness theory was that, to an ordinarily skilled artisan, it would have been obvious to combine the '909 patent's amlodipine maleate with a January 1977 article (Berge, "Pharmaceutical Salts," *J. Pharm. Sci.* 66(1):1-19 (Jan. 1977)), whose Table 1 showed "53 FDA-approved, commercially marketed anions, including benzene sulphonate, that are useful for making pharmaceutically-acceptable salts, and lists the relative frequency of which each was used as a percentage based on the total number of anions or cations in use through 1974. Berge discloses that benzene sulphonate had a frequency of use of 0.25%." App. 8a.

Even so, one of ordinary skill in the art who looked beyond the '909 patent in April 1986 would have found an unlimited number of acids from which he or she might try to make a pharmaceutically acceptable salt of amlodipine by engaging a trial-and-error process. C.A. App. 884. Certainly, nothing pointed especially to the besylate anion: Besylate was a rarely used anion, present (as the Berge article showed) in only ¼ of 1 percent of drugs approved by the FDA as of 1977 (*i.e.*, one out of 400). By 1984, when amlodipine besylate was invented, there were only *two* drugs that had been approved by FDA in a besylate salt form: mesoridazine besylate and atracurium besylate. Neither was a cardiovascular drug, and neither belonged to the class of dihydropyridine compounds. Neither provided any information about the likelihood of even forming an amlodipine besylate salt, or what its properties might be. C.A. App. 887, 242-52.

As the district court here found: "As to whether the besylate salt is an actual improvement over the maleate, the Court recognizes that while not superior to the maleate salt in every category, the besylate salt clearly and unexpectedly illustrates a superior combination of properties when

compared to what was suggested as the preferred preparation, the maleate salt in the '909 patent. In addition to the evidence supplied by the exhibits in the patent, the Court notes the objective consideration that Pfizer would not have changed from the maleate, into which it had invested both time and research dollars, to seek out a very strange and rare besylate salt, absent an extremely good reason." App. 65a-66a. Indeed, the Court concluded its opinion with this extraordinary praise for Pfizer's amlodipine besylate invention: "[T]he Court finds it to be an exceptional discovery, the besylate salt which finally produced a reliable delivery system." App. 67a.

3. On April 14, 2003, Apotex filed Abbreviated New Drug Application ("ANDA") No. 76-719 with the FDA, seeking to bring to market a generic version of Pfizer's Norvasc®. Apotex's ANDA represented that its proposed generic product was the same as Pfizer's Norvasc®, and that the '303 patent was not expired, but Apotex further averred that it was entitled to marketing approval because, in its view, the '303 patent was invalid and unenforceable. Under the Hatch-Waxman Act, the filing of this ANDA was itself an act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). Accordingly, on July 30, 2003, Pfizer sued Apotex in order to defend its patent and defer any generic entry into the marketplace until after the pediatric exclusivity period for the '303 patent had expired, on September 25, 2007. App. 1a-2a; *see Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1275 (D.C. Cir. 2004) (explaining that 21 U.S.C. § 355a "authorizes an extra six-month pediatric exclusivity period following expiration of a drug patent for a patent holder that has satisfactorily conducted pediatric testing of its drug upon the FDA's request . . . .").

4. The District Court for the Northern District of Illinois held a bench trial from January 9 through January 17, 2006. On January 18, 2006, the district court issued its findings and conclusions, pursuant to FED. R. CIV. P. 52(a), from the bench, holding, *inter alia*, that claims 1-3 of the '303 patent

were nonobvious, and indeed represented "an exceptional discovery" and "an invention in its own right." App. 67a. Accordingly, the district court ordered that the FDA not approve Apotex's ANDA 76-719 prior to September 25, 2007. App. 67a-68a. That September 25, 2007 date was six months after the March 25, 2007 expiration of the '303 patent, representing the six additional months of pediatric exclusivity granted to Pfizer for amlodipine besylate pursuant to 21 U.S.C. § 355a(c)(2)(A)-(B).

5. On March 22, 2007, a panel of the Federal Circuit (with one judge concurring in the result only) reversed. Applying a version of its teaching-suggestion-motivation requirement, which has been criticized by this Court, the court held that "evidence of record easily satisfies us that a reasonable fact-finder could only conclude that Apotex has shown by clear and convincing evidence that the skilled artisan would indeed have been so motivated to combine the prior art to produce the besylate salt of amlodipine," and that, "contrary to the district court's finding, a reasonable fact-finder could only conclude that a skilled artisan would have had a reasonable expectation of success with the besylate salt of amlodipine." App. 19a.

6. Pfizer filed a petition for rehearing and rehearing *en banc*. While that petition was pending, this Court decided *KSR International Corp. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007), which criticized the Federal Circuit's "rigid and mandatory" teaching-suggestion-motivation test and emphasized the important role of "unpredictability" in the nonobviousness analysis (*e.g.*, where elements combine in an "unexpected and fruitful manner," that will support a finding of nonobviousness). *Id.* at ___, 127 S. Ct. at 1740, 1741. Although Pfizer promptly filed a letter brief under FED. R. APP. P. 28(j), explaining why *KSR* supported rehearing, neither the panel nor the Federal Circuit *en banc* reconsidered the panel opinion to take *KSR* into account: the petition was denied on May 21, 2007, and the mandate was ordered to be issued immediately upon the denial. App. 40a.

Three judges dissented from the decision denying *en banc* rehearing. Judge Newman noted that "[b]oth sides acknowledge that the effects of chemical changes on properties of medicinal products is not predictable," and that the panel decision conflicted with the last sentence of 35 U.S.C. § 103(a), which commands that "[p]atentability shall not be negatived by the manner in which the invention was made." App. 41a. She also stressed that "[t]he ruling in this case has important policy as well as legal implications." App. 41a.

Judge Lourie dissented because "the panel failed to defer to fact-findings made by the district court that were not clearly erroneous regarding the unexpected properties of amlodipine besylate" (App. 47a), because "the panel improperly placed greater importance on the therapeutic value of a claimed compound over the value of its physical properties" (App. 47a), and because "the panel . . . found that the invention was the result of routine experimentation, and therefore was not patentable," which he (like Judge Newman) viewed as in conflict with the last sentence of 35 U.S.C. § 103(a). App. 48a. In addition, Judge Lourie noted that after *KSR*, a showing of unexpected properties (beyond biological properties) will take on a special importance in the pharmaceutical field, yet the panel opinion disdained such unexpected, non-biological properties entirely. Calling these issues ones of "exceptional importance," Judge Lourie voted to rehear the case, and dissented from the Federal Circuit's failure to do so. App. 49a.

Judge Rader also dissented. Like Judges Newman and Lourie, he chided the panel for discarding the undisputed testimony and evidence that "the properties of new pharmaceutical salt forms are entirely unpredictable" (App. 50a), noted that the panel's "obvious to try" approach was an ill fit in pharmaceutical cases (App. 50a-51a), and expressed concern that the panel's narrow focus on the fact that the besylate salt "showed no superior *therapeutic value*" was a myopic focus on just one of many properties of a

pharmaceutical product: "Although the maleate salt form was also therapeutically effective, the besylate form was still a significant improvement because it overcame the stability and processing problems that could have prevented successful commercial marketing." App. 51a (emphasis added).

Also like his dissenting colleagues, Judge Rader objected to the panel's disregard for the "patentability shall not be negatived by the manner in which the invention was made" requirement of 35 U.S.C. § 103(a); he explained why this had profound consequences for not just this case, but for all pharmaceutical patents: "Many if not most pharmaceutical inventions are discovered through a routine screening protocol or through an established trial and error process. Pharmaceutical inventions discovered by these routine screening methods include not only new formulations and salt forms, but also include the active pharmaceutical compounds themselves. Thus, 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." App. 51a.

REASONS FOR GRANTING THE WRIT

The importance of the issues in this case, as explained by the three dissenting judges in the Federal Circuit, would surely qualify this case for plenary review. But that is not a realistic possibility in this case, which will become moot no later than September 25, 2007, when Pfizer's pediatric-exclusivity period for amlodipine besylate comes to an end. So as a practical matter, the only chance of securing any relief from the erroneous judgment of the Court of Appeals in this case is to ask this Court to issue a GVR order — that is, to grant the petition, vacate the judgment below, and remand with instructions for the Federal Circuit to reconsider its decision in light of *KSR International Co. v. Telefle, Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007). The Federal Circuit

had every opportunity to do that, because *KSR* was handed down while Pfizer's rehearing petition was pending, but it failed to do so.

If this Court cannot review the case before September 25, 2007, then Pfizer alternatively requests the Court to vacate the judgment below and remand with instructions to dismiss under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994). That outcome will avoid the inequities of having Pfizer saddled with the potential collateral-estoppel effect of a decision whose further review was prevented by the happenstance of patent expiry, and having future litigants (particularly in pharmaceutical cases) subject to an obviousness precedent of questionable correctness, and which took no account of this Court's *KSR* decision.

I. THIS CASE WARRANTS A GVR ORDER AS THE COURT OF APPEALS' DECISION IS PLAINLY IN TENSION WITH THIS COURT'S DECISION IN *KSR v. Teleflex*, WHICH THE FEDERAL CIRCUIT GAVE NO INDICATION OF CONSIDERING

This case is a textbook example of the type of case that warrants a GVR order, an order that this Court has described as an "integral part of this Court's practice, accepted and employed by all sitting and recent Justices." *Lawrence v. Chater*, 516 U.S. 163, 166 (1996). Such orders, which provide a vital mechanism for "conserv[ing] the scarce resources of this Court," are appropriate whenever each of three elements are met: (1) there have been "intervening developments, or recent developments that [the Court has] reason to believe the court below did not fully consider [that] 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," (2) "it appears that such a redetermination may determine the ultimate outcome

of the litigation," and (3) the "equities of the case" favor a GVR order. *Id.*

All three are clearly present here. Shortly after the Federal Circuit issued its decision below invalidating the '303 patent on obviousness grounds, this Court's decision in *KSR* interpreted section 103(a) in a manner that cast substantial doubt on the Federal Circuit's then-prevailing teaching-suggestion-motivation requirement, demonstrating, at the very least, a "reasonable probability" that this "intervening development" might change the panel's obviousness analysis. And, as the Court of Appeals' obviousness determination was the sole basis on which it invalidated the patent, a different outcome on that question would almost certainly "determine the ultimate outcome of the litigation." Finally, on the equities, the profound consequences that the decision in this case will carry for pharmaceutical research and development in this country strongly suggest that the obviousness determination should be made with the benefit of an explicit consideration of this Court's latest guidance on the issue.

A. The Federal Circuit Invalidated The '303 Patent Based On a Version of Its Teaching-Suggestion-Motivation Test, Which Has Been Criticized By This Court.

Two issues here are beyond dispute—the Federal Circuit's obviousness analysis in this case was the *sole* basis on which it relied in denying Pfizer relief, and its obviousness analysis was predicated solely on pre-*KSR* obviousness precedents from that Court. Apotex conceded that its ANDA product (generic amlodipine besylate) would infringe the '303 patent. App. 35a-36a. And, while Apotex sought to defend against the infringement claim both on invalidity and unenforceability grounds, the only issue that the Federal Circuit reached was invalidity. App. 36a-37a. Moreover, the sole basis the court cited in declaring the patent invalid was its conclusion that the invention claimed in the '303

patent was obvious. In the panel's words: "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." App. 37a.

In reaching that conclusion, the panel naturally relied on the then-current Federal Circuit obviousness standards. In particular, the court took its test from *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006), *pet. for cert. filed*, 75 U.S.L.W. 3484 (No. 06-1207, Mar. 5, 2007), 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." App. 18a. And the court's treatment of the "motivation" element in that test clearly reflected that the court used that prong as a shorthand for the Circuit's teaching-suggestion-motivation 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.'" App. 19a-20a (quoting *DyStar*, 464 F.3d at 1361). Applying *DyStar*'s implementation of the teaching-suggestion-motivation test, the court concluded 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." App. 23a.

The court then turned to consideration of the other factor from the *DyStar* test—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. At trial, Pfizer's expert witness had testified, 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." App. 42a (Newman, J., dissenting) (internal quotation marks omitted). Based on such testimony, 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,'" and, accordingly, that it was not obvious. App. 47a (Lourie, J., dissenting) (quoting district court transcript).

The panel, however, rejected the obviousness determination, essentially holding, as one of the judges who dissented from the denial of rehearing noted, that whenever an "invention was the result of routine experimentation," it is "not patentable," notwithstanding that the results of that experimentation may have been surprising or unexpected. App. 48a (Lourie, J., dissenting). *See also* App. 31a (classifying Wells' efforts in discovering amlodipine besylate as "nothing more than routine application of a well-known problem-solving strategy" (internal quotation marks omitted)). To be sure, the court below attempted to limit that result to "the particularized facts of this case," App. 29a (emphasis omitted), but nowhere is any such limiting principle apparent in its opinion. As a consequence, numerous inventions in the pharmaceutical industry will be put at risk, as that industry is one in which new, surprising, and important advances often result from similar "routine experimentation," or trial-and-error efforts.

B. *KSR* Substantially Altered The Federal Circuit's Obviousness Framework

The Federal Circuit issued its opinion before the Court decided *KSR*, and *KSR* altered the obviousness landscape in at least two ways directly relevant here. *First*, the Court's opinion in *KSR* expressly eliminated the use of the Federal Circuit's teaching-suggestion-motivation test as the basic test

for obviousness. According to this Court, "[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation." 550 U.S. at ___, 127 S. Ct. at 1741. And, in particular, with regard to that test's focus on "motivation," the Court noted that "[i]n determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls." *Id.* at ___, 127 S. Ct. at 1741-42. Thus, the Court of Appeals' extensive focus on "motivation" in this case stands in sharp contrast to the approach articulated by this Court in *KSR*.

Second, the Court in *KSR* reaffirmed the principle that where combinations of known elements 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 ___, 127 S. Ct. at 1742; *see also id.* at ___, 127 S. Ct. at 1738 (combination is obvious "when it does no more than yield predictable results"). But, the Court expressly noted that when the combined elements work together in an "unexpected and fruitful manner," that surprising result supports a finding of nonobviousness. *Id.* at ____, 127 S. Ct. at 1740. At a minimum, this suggests that *KSR* adopted a quite different understanding of the importance that unexpected results play in the obviousness determination. In turn, that shows a "reasonable probability" that the Federal Circuit might decide this case differently after considering *KSR*.

The *KSR* opinion also offers further evidence confirming the need for a GVR order here. The Court's opinion directly referenced *DyStar*'s obviousness standard—the very standard that the court below relied on here. While acknowledging that in *DyStar* the Federal Circuit had "elaborated a broader conception of the TSM test," the Court expressly declined to rule on whether or not that standard met *KSR*'s demands, saying only that that "is a matter for the

Court of Appeals to consider in its future cases." 550 U.S. at ___, 127 S. Ct. at 1743. That consideration should have occurred here, and it should occur (with specific direction to do so) on remand.

In short, *KSR* changed the Federal Circuit's longstanding approach to obviousness, and the Federal Circuit's now-suspect pre-*KSR* teaching-suggestion-motivation framework was the *sole* underpinning to the Federal Circuit's decision in this case. Thus, there is a "reasonable probability" that, with a proper consideration of *KSR*, the Federal Circuit would come to a different result on obviousness. *See Chater*, 516 U.S. at 167. And, if it does, that change would almost certainly result in a different "ultimate outcome" below. *Id.*

C. The Equities Confirm The Need For A GVR Order

The equities of the case further confirm the appropriateness of a GVR order here. Indeed, the judges who dissented from the denial of rehearing expressly referred to the "exceptional importance" of the issues at stake here, and they were right. First, the Federal Circuit's decision is vitiating Pfizer's pediatric exclusivity for Norvaxc®, resulting in significant financial losses to Pfizer and its shareholders. Already, the decision below has enabled two generic products to compete against Pfizer's product, in derogation of Pfizer's exclusivity. Additional comopetitors might also be approved if the decision is not corrected, resulting in deeper financial losses. More importantly, though, the decision below does not merely affect Pfizer and Norvasc®. Rather, the decision below carries profound consequences for pharmaceutical research and development in general.

As the judges who dissented from the denial of rehearing noted, "[t]he panel decision 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 incentive [for]

development of new products." App. 42a (Newman, J., dissenting). In essence, under the panel decision, an invention will not be patentable any time "that the invention was the result of routine experimentation," App. 48a (Lourie, J., dissenting), a troubling result in that "methodical experimentation is fundamental to scientific advance, and particularly for biological and medicinal products, where small change[s] can produce large differences," App. 42a (Newman, J., dissenting). In fact, as Judge Rader observed in dissent, 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." App. 51a (Rader, J., dissenting).

In language directly on point here, the panel opinion below, quoting *DyStar*, observed that "[o]bviousness is a complicated subject requiring sophisticated analysis" based on "careful reading of the full text of a group of related precedents." App. 27a (internal quotation marks omitted). Without "careful, candid, and complete legal analysis," the court continued, "much confusion about the law arises." App. 27a (internal quotation marks omitted). Unfortunately, the Court of Appeals failed to heed its own admonition and failed to provide a "complete legal analysis" that included consideration of *KSR*, this Court's most recent pronouncement on the subject. GVR is particularly appropriate in this light.

II. IF THE COURT OF APPEALS' DECISION IS NOT REVIEWED PRIOR TO SEPTEMBER 25, 2007, THE CASE WILL BECOME MOOT, AND IN THAT EVENT THE PETITION SHOULD BE GRANTED WITH DIRECTIONS TO VACATE THE COURT OF APPEALS' DECISION UNDER *United States v. Munsingwear* AND *U.S. Bancorp Mortgage Corp. v. Bonner Mall Partnership*

As we have shown in Section I, the Court of Appeals' invalidation of Pfizer's '303 patent has profound implications for virtually all pharmaceutical patents. The three opinions dissenting from the denial of rehearing *en banc* in the Federal Circuit confirm that the issue presented here is one of "exceptional importance" (App. 46a (Lourie, J., dissenting)), which "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." App. 51a (Rader, J., dissenting). On those terms alone, the decision below would merit plenary review by this Court.

As a practical matter, though, it will be all but impossible for this Court to decide this case on full briefing and argument. The Federal Circuit's denial of rehearing—in which it failed to reconsider its decision in light of *KSR*—came on May 21, 2007. The '303 patent expired on March 25, 2007, however, which means that the only rights Pfizer has left are its rights to six additional months of pediatric exclusivity. Because the period of pediatric exclusivity associated with the '303 patent will expire on September 25, 2007 (the Tuesday before the first Monday in October), this case will become moot if it is not reviewed before then. Thus, Pfizer is asking this Court to issue a GVR order—and an expedited one, at that—so that the Federal Circuit can properly reconsider its decision in light of *KSR* before the issue becomes an academic one.

If the Court cannot dispose of this petition before September 25, however, then Pfizer requests that the Court grant the petition and vacate the judgment of the Federal Circuit pursuant to *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950) and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994). Under those decisions, the "established practice of the Court in dealing with a civil case from a court in the federal system which has become moot while on its way here or pending our decision on the merits is to reverse or vacate the judgment below and remand with a direction to dismiss." *Munsingwear*, 340 U.S. at 39. "That procedure clears the path for future relitigation of the issues between the parties and eliminates a judgment, review of which was prevented through happenstance. When that procedure is followed, the rights of all parties are preserved; none is prejudiced by a decision which in the statutory scheme was only preliminary." *Id.* at 40.

There is no question but that the mootness here would be caused by the "happenstance" of the statutory expiration of Pfizer's patent rights, combined with the timing of both this suit and the Federal Circuit's decision not to rehear the case. When combined with Pfizer's vigilance in filing this petition, it cannot possibly be said that Pfizer "caused the mootness by voluntary action," disentitling it from the equitable relief of vacatur under *U.S. Bancorp*, 513 U.S. at 24. "[M]ootness by happenstance provides sufficient reason to vacate." *Id.* at 25 n.3.*

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* Under the FDA's April 18, 2007 letter to all ANDA applicants/holders for amlodipine besylate tablets, issued after the panel decision in this case, the FDA concluded that it could not approve any ANDAs for amlodipine besylate (except for Mylan's already-approved ANDA) until the Federal Circuit issued its mandate. *See Mylan Labs. v. Leavitt*, ___ F. Supp. 2d ___, 2007 WL 1241884 (D.D.C. April 30, 2007). Upon denying rehearing and rehearing *en banc* in this case on May 21, 2007, the Federal Circuit ordered that the mandate issue *instanter* (App. 40a),

Indeed, the equities would all point to vacatur in the case of mootness. In two challenges from other generic manufacturers, two other district courts have upheld the '303 patent against obviousness challenges, with detailed findings of fact to support those judgments. *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). Those manufacturers have claimed that the collateral-estoppel authority of the March 22, 2007 panel decision in this case resolves their appeals from those judgments and allows them to bring to market generic versions of Norvasc®. In the case of Mylan, which has already brought a generic version to market based on this authority, that company has unfairly asserted, in a motion for summary reversal in the Federal Circuit, that the collateral estoppel effect of the obviousness decision below bars Pfizer from suing them even for the infringement damages suffered by Pfizer prior to patent expiration. *See Pfizer Inc. v. Mylan Labs., Inc.*, No. 2007-1194 (Fed. Cir. Mar. 29, 2007). It would be inequitable to allow the judgment in this case to stand, thereby potentially giving rise to assertions of collateral estoppel against Pfizer, were this case to become moot by the happenstance of the passage of time. *See United States v. Hamburg-Amerikanische Packet-Fahrt-Actien Gesellschaft*, 239 U.S. 466, 478 (1916) ("the ends of justice exact that the judgment below should not be permitted to

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and Apotex launched its generic amlodipine besylate on May 24, 2007. Pfizer has asked this Court to order that mandate recalled and stayed. If that does not occur, it is possible that this case became moot with the issuance of the Federal Circuit's mandate; in that event, the judgment here should be vacated, as the case for vacatur based on mootness by happenstance is no less strong under those circumstances.

stand when, without any fault of the [petitioner], there is no power to review it upon the merits").

Viewing the issue more broadly, the equities also counsel against leaving the judgment of the Court of Appeals on the books as binding precedent. For one, as noted above and by the dissenters from the denial of rehearing *en banc*, the decision has profound and negative consequences for the patentability of novel pharmaceutical compositions when the ground for patentability is found in developments other than therapeutic effectiveness (such as found here in the superior manufacturing qualities of amlodipine besylate). The fact that this decision was reached without the benefit of considering this Court's intervening decision in *KSR* makes the case for vacatur here even more compelling; district courts should not be forced to follow the decision below as precedent, particularly when there are substantial questions regarding its validity in view of *KSR*. Vacatur here will therefore clear the path for this issue to be litigated again in future cases, where appellate review will not be impeded by the happenstance of patent expiry, and where the courts hearing the cases will have the full opportunity to consider *KSR*, this Court's most recent pronouncement on the statutory doctrine of obviousness. In that light, if "the demands of 'orderly procedure' cannot be honored" in this case, then "the public interest is best served by granting relief." *U.S. Bancorp*, 513 U.S. at 27 (quoting *Munsingwear*, 340 U.S. at 41) (internal citation omitted).

CONCLUSION

The petition should be granted, and the judgment of the Court of Appeals vacated.

Respectfully submitted,

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