No. 06A1131

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

---

REPLY IN SUPPORT OF APPLICATION TO RECALL AND STAY THE MANDATE PENDING DISPOSITION OF PETITION FOR WRIT OF CERTIORARI

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

To the Honorable John Paul Stevens, Associate Justice of the United States Supreme Court:

Apotex's Memorandum in Opposition ("Opp.") fails to overcome Pfizer's demonstration in its Application ("Appl.") of a compelling need for an order recalling and staying the mandate in this case. In its application, Pfizer showed that each of the four elements the Court considers in deciding such applications is present here. Apotex's opposition, which turns on flawed arguments and demonstrably false characterizations of the facts and procedural posture of the case, does not show otherwise.

I. There is more than a reasonable probability that the Court will grant certiorari.

To obtain a recall, Pfizer must first show that there is a reasonable probability that the Court will grant certiorari. As Pfizer detailed in its application, the Federal Circuit invalidated claims 1-3 of Pfizer's '303 patent based on a flawed theory of obviousness that (as three Judges dissenting from the denial of *en banc* rehearing stated) will have profoundly negative consequences for pharmaceutical patent protection. Moreover, the Federal Circuit reached that result without any apparent consideration of the Court's most recent guidance on the subject of obviousness, *KSR Int'l Corp. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007), making this case a textbook example for the Court's exercise of its GVR power.

Apotex mounts a three-pronged response; each prong is fatally flawed. *First*, Apotex appears to contend that a GVR order somehow does not count for purposes of the likely-to-grant-certiorari test, *see* Opp. at 3-4. That is at best a confusing response, as the 'G' in GVR stands for "granting certiorari." Nor would Apotex's rule make any sense: GVR orders vacate the decision below and return the case to the posture in which it was before the appellate court reached its initial decision. If there is a reasonable probability that the Court will enter such an order, and

there clearly is here, then it only makes sense that the parties should be restored, as closely as possible, to their pre-decisional posture pending the new decision.

Second, Apotex's suggestion that Pfizer "does not claim that its petition should be granted because this case merits plenary review," aside from being irrelevant, is wrong to boot. *See* Opp. at 3, 4. In its Petition, Pfizer expressly stated that "[t]he 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." Pet. at 8. Rather, Pfizer acknowledged that, given the short remaining duration of the pediatric exclusivity period, combined with the Court's calendar, obtaining that plenary review will be practically impossible. But that is no reason to deny Pfizer relief. If anything, the order recalling and staying the Federal Circuit's mandate is even more crucial under those circumstances, as Pfizer explained both in its application and its motion to expedite consideration of the petition.

Third and finally, Apotex's claim that *KSR* cannot support a GVR here because the parties had "brought *KSR* to the attention of th[e] court of appeals" before the court denied rehearing *en banc* is belied by the Court's own precedent. *See* Opp. at 4. In *Lords Landing Village Condominium Council of Unit Holders v. Continental Insurance Co.*, 520 U.S. 893 (1997), resolution of the case turned on a question of state law. After the federal court of appeals decided the state-law question and issued its mandate, the state supreme court announced a new decision calling the circuit court's resolution of the state-law question into doubt. There, as here, the parties brought the decision to the attention of the appeals court. There (unlike here), the court actually issued a written order whose sole purpose was to discuss whether the new decision "required a different disposition of this case." *Id*. at 898 (Rehnquist, C.J., dissenting) (describing lower court's order) (internal quotation marks omitted). And the federal court of appeals

resolved that question, concluding that "we are of the opinion the said petition and motions are without merit." *Id*. (quoting lower court decision) (internal quotation marks and alterations omitted).

This Court had no difficulty concluding that the intervening state-court authority required a GVR. According to this Court's opinion, the intervening decision provided "reason to question the correctness of the Court of Appeals' decision," and the court of appeals' "ambiguous statement" that the petitioner's request for reconsideration was "without merit" did not prove that the appeals court had taken the new decision into account. *Id*. at 896-97. Here, the Federal Circuit did not even issue an "ambiguous statement"—it stood silent on the effect of *KSR*. Apart from the bare facts that the *KSR* decision issued before the court below denied the petition for rehearing, and that one dissenting judge made a single reference to that decision, there is no indication that the court below considered the ramifications of *KSR* for its decision. That silence was particularly ironic, given that the Federal Circuit below (Pet. App. 27a) and in *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006), had exhorted litigants to engage in "careful, candid, and complete legal analysis" by "gleaning the law . . . from careful reading of the full text of a group of related precedents for all they say that is dispositive and for what they hold." Pfizer is surely entitled to have its patent rights adjudicated in the same "careful, candid, and complete" way, and that is why a grant of certiorari (in the context of a GVR order) is reasonably probable.

II. There is more than a "fair prospect" that Pfizer will prevail.

Apotex's arguments regarding the second inquiry under *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers), are equally devoid of merit. Pfizer showed in its application that "there is a fair prospect that a majority of the Court will conclude that the

decision below was erroneous," *i.e.*, that this Court will likely vacate the decision below, and remand the case for further consideration in light of *KSR*. Appl. at 9-12. Apotex's primary response is to argue that such a vacatur would not satisfy the second prong of the test because only a "merits" ruling by this Court, as opposed to a GVR order, would affirmatively demonstrate error. Apotex is wrong. As the Court emphasized in *Lawrence v. Chater*, 516 U.S. 163 (1996) (per curiam), a GVR order stems from the same source of statutory authority that permits vacatur in any other case; it is no different, for purposes of the recall analysis, from a vacatur ordered after plenary review. *See id.* at 166. Apotex's exclusive focus on the ultimate outcome on remand is thus misplaced—it is the likelihood of vacatur by *this* Court that suffices to satisfy the second prong. *See, e.g.*, *Rostker*, 448 U.S. at 1308 (looking to the likely action by "a majority of th[is] Court" to decide second prong).

In any event, Apotex is also wrong in disputing that *KSR* will likely require a different outcome on remand. Apotex simply ignores Pfizer's showing, at page 11 of the application, that in the course of rejecting an unduly mechanical application of the "teaching, suggestion, and motivation" test applied by the Federal Circuit in the decision below, this Court affirmatively explained that in a case like this one, where combined elements come together in an "unexpected and fruitful manner," *KSR*, 127 S. Ct. at 1740, that will support a finding of nonobviousness. Moreover, Apotex concedes (Opp. at 8) that *KSR* expressly discussed *DyStar*, upon which the Federal Circuit's decision in this case relied, and went out of its way to observe that *DyStar*'s continuing validity was "not now before us," 127 S. Ct. at 1743—yet the Federal Circuit has not yet reconsidered *DyStar* in light of *KSR* (a petition for certiorari, No. 06-1207, is pending in *DyStar* and is scheduled to be considered by this Court at its June 7 Conference). Whatever the

outcome of the petition in *DyStar*, it is plain that the harmonization of the *DyStar* approach with *KSR* has not yet occurred; the GVR order requested by Pfizer here will allow that to happen.

III. Pfizer will suffer irreparable harm absent a recall.

Contrary to Apotex's claim, denial of relief will indeed result in irreparable harm to Pfizer. Apotex's suggestion that Pfizer will have some sort of damages remedy is false. *See* Opp. at 8-9. The *pediatric exclusivity* period does not extend the *patent* term. Rather, it is merely a period during which the FDA will not approve competitors' ANDAs. Thus, unlike the case during the patent term, there is no private right of action for "violating" the period of pediatric exclusivity. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (noting that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with FDA regulations). This in turn means that without the relief Pfizer seeks here, a remedy down the road is likely to be a hollow victory at best.

Similarly flawed is Apotex's claim that "the FDA has indicated that Pfizer's pediatric exclusivity period still will apply" to Pfizer's other competitors. *See* Opp. at 10. As the FDA states in the very letter that Apotex cites, its position is that the competitors' ANDAs are blocked "during the period before the mandate issues." *See* Opp. Ex. A at 9. As that language suggests, the remedy Pfizer seeks here is vitally important to protecting Pfizer from the irreparable harm that will result if the market is flooded with generic products.

Indeed, just yesterday, the Federal Circuit issued orders in two cases that will work even more irreparable harm upon Pfizer. In its application (at 6) and in its petition for certiorari (at 1 n. * & 18), Pfizer noted two other cases (involving Mylan and Synthon) in which Pfizer has asserted the same patent. The district courts in those cases had concluded, based on extensive

findings of fact, that claims 1-3 of the '303 patent are valid and enforceable. Yesterday, however, the Federal Circuit reversed both of those judgments (Appeal Nos. 2007-1045 and 2007-1194), apparently based on its decision in this case. *See* U.S. Court of Appeals Disposition Sheet, June 5, 2006, *available at* http://www.fedcir.gov/daily.txt (last visited June 6, 2007). In short, absent the relief Pfizer seeks here, it will be irrevocably deprived of the exclusivity rights that Congress guaranteed it under the Better Pharmaceuticals for Children Act.

IV. The equities support recall of the mandate.

Finally, Apotex errs in its treatment of the final inquiry under *Rostker*, which considers the balance of the equities. *First*, Apotex ignores that this factor becomes relevant only "in a close case," 448 U.S. at 1308, which, as the foregoing discussion demonstrates, this is not. Recall is therefore appropriate here without regard to the final inquiry.

Second, Apotex mischaracterizes both the relative interests of the parties and the public. As shown above, Pfizer will suffer irreparable harm in the absence of recall. The only reason that Mylan and other competitors are presently in the marketplace is because of the erroneous and incompletely considered decision below; if that decision can be reconsidered before this dispute becomes moot, then (contrary to Apotex's repeated insinuations, *e.g.*, Opp. at 10, that "Mylan already is on the market and will remain on the market irrespective of how this appeal is decided") it may be appropriate for a federal court to shape further equitable relief that will prevent Mylan and other competitors from continuing their marketing of a competing generic drug, and restoring to Pfizer some of its remaining exclusivity.

And Apotex fundamentally misstates the public interest by equating the interest of the public with the presence of "generic competition." Opp. at 11. In the Hatch-Waxman Act, the Congress, which is the ultimate arbiter of the public interest, has determined that the relevant

public interests in this area are set by drawing the appropriate balance between the exclusivity of patentees, including an applicable pediatric exclusivity period, and competition from generic manufacturers. There is no public interest in causing a major pharmaceutical manufacturer to be deprived of the proper benefits of an exclusivity to which it is properly and statutorily entitled. *See, e.g., Mylan Labs., ,Inc. v. Thompson,* 389 F.3d 1272, 1284 (D.C. Cir. 2004).

Third and finally, Apotex's claim of "dilatory conduct" by Pfizer (Opp. at 12) is truly breathtaking. As support, Apotex cites *Ruckelshaus v. Monsanto Co.*, 463 U.S. 1315 (1983) (Blackmun, J., in chambers), a case where the applicant (the EPA Administrator) filed the application for stay *seven weeks* after the district court judgment, *and* sought a 30-day extension for the filing of his jurisdictional statement. *Id.* at 1317-18. Here, Pfizer filed its complete petition for certiorari, and its application for recall and stay, a mere *eight days* after the Federal Circuit denied rehearing and ordered its mandate issued. Nor can Pfizer be faulted for not delaying the proceedings with further efforts to have the Federal Circuit recall and stay its own mandate—Apotex itself was the party that raised this issue when it moved for expedited issuance of the mandate (Appl. Ex. A), and the parties had already joined issue and been heard on the subject (Appl. Ex. B). A further application by Pfizer (which surely would have been futile in light of that court's decision to issue the mandate *instanter*), would only have delayed this case further. Because of the approaching expiration of pediatric exclusivity on September 25, 2007, this sort of additional delay would have caused even more harm—this time, self-inflicted harm—to Pfizer. Even if the issue had not been joined in the Federal Circuit, the circumstances of this case are surely sufficiently "most extraordinary" under this Court's Rule 23.3 to merit relief.

The Application should be granted, and the mandate of the Federal Circuit recalled and stayed.

Respectfully submitted,

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

Dated: June 6, 2007

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