PFIZER INC.,

Plaintiff–Appellee,

v.

MYLAN LABORATORIES, INC.
and MYLAN PHARMACEUTICALS, INC.,

Defendants–Appellants.

Appeal from the United States District Court for the Western District of Pennsylvania in case no. 2:02-CV-1628, Judge Terrence F. McVerry

RESPONSE OF PLAINTIFF–APPELLEE PFIZER INC. PURSUANT TO THE COURT'S MARCH 23, 2007 ORDER

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MARCH 26, 2007

No. 2007-1194

United States Court of Appeals

for the

Federal Circuit

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MARCH 26, 2007

CERTIFICATE OF INTEREST

Counsel for the appellee, Pfizer Inc., certifies the following:

1. The full name of every party or amicus represented by me is:

   Pfizer Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

   Kaye Scholer LLP; Milton Sherman, Richard G. Greco, Betty A. Ryberg, Joseph V. Saphia, Daniel A. Boglioli, Sapna Walter Palla, Regina O. Kent, Donald Cameron, and David Bickart.

   Thorp, Reed & Armstrong, LLP; C. James Zeszutek, and John J. Richardson.

March 26, 2007

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PRELIMINARY STATEMENT

On March 23, 2007, this Court directed the parties to submit briefs regarding the effect of the Court's ruling in *Pfizer Inc. v. Apotex, Inc.*, Docket No. 2006-1261 (the "*Apotex* Decision") on ANDA approvals and pediatric exclusivity. As explained herein, the Court's Order held Mylan's motion for a stay in abeyance pending the further consideration of these briefs, and also temporarily stayed the district court's order in an attempt to preserve the *status quo* while it considered the parties' submissions.

However, Mylan took advantage of this Court's order on Friday to irrevocably alter the *status quo.* Approximately one hour after Pfizer received this Court's Order, and while Pfizer was seeking clarification of it, Mylan announced that it had commercially launched its generic Norvasc® tablets. Mylan's launch permanently altered the market place and caused Pfizer to suffer severe and irreparable injury. Pfizer irrevocably will lose at least part of the benefit of the pediatric exclusivity period, which has a limited duration of six months. Moreover, it will lose very substantial sales on its blockbuster drug Norvasc® for which it has no clear and adequate legal remedy. Pfizer estimates the value of its pediatric exclusivity rights to be approximately $1 billion.

Pfizer shortly will file a petition for panel and *en banc* rehearing of this Court's March 22, 2007 decision in *Apotex.* Pfizer respectfully requests that

the Court lift its temporary stay in this matter while it considers Pfizer's petition for rehearing. Because Pfizer's injury is both severe and irreparable, Pfizer further requests that the Court lift the temporary stay forthwith. Once the temporary stay is lifted, the district court's amended judgment will have full force and effect. Based on the FDA's prior rulings, Pfizer expects that, based on the § 271(e)(4)(A) order in the amended judgment, the FDA will implement Pfizer's pediatric exclusivity pending this Court's resolution of its petition for rehearing.

STATEMENT OF FACTS

Events Preceding This Court's March 23, 2007 Order

On March 16, 2007, the U.S. District Court for the Western District of Pennsylvania entered judgment in Pfizer's favor in its Hatch-Waxman action against Mylan (the "Amended Judgment"). The action was brought pursuant to 35 U.S.C. § 271(e)(2)(A) and alleged that Mylan, by filing an Abbreviated New Drug Application ("ANDA") for generic Norvasc® tablets, infringed Pfizer's U.S. Patent No. 4,879,303 (the "'303 patent). Pursuant to 35 U.S.C. § 271(e)(4)(A), the Amended Judgment prohibits final approval of Mylan's ANDA until a date not earlier than the expiration date of the '303 patent. The Amended Judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), also enjoins Mylan from commercially

marketing its generic Norvasc® tablets until the '303 patent expires at midnight on March 25, 2007.[1]

On March 16, 2007, Mylan moved in the district court to stay the § 271(e)(4)(A) order in the Amended Judgment pending its appeal to this Court. On March 19, 2007 the district court denied Mylan's motion. Thereafter, on March 20, 2007, Mylan moved for a stay of the § 271(e)(4)(A) order in this Court.

On March 22, 2007, this Court issued the *Apotex* Decision, holding that claims 1 through 3 of the '303 patent, the only claims Pfizer asserted in its Hatch-Waxman patent infringement action against Apotex, are invalid as obvious pursuant to 35 U.S.C. § 103. Mylan supplemented its motion for a stay pending appeal based on the *Apotex* Decision on March 22, 2007, and again requested the district court to stay its order. Mylan's request was denied.

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[1] The district court's original judgment enjoined marketing through September 25, 2007, when Pfizer's period of pediatric exclusivity expires, but did not contain an order under 35 U.S.C. § 271(e)(4)(A). After FDA informed Pfizer that it would not effectuate pediatric exclusivity by rescinding its approval of Mylan's ANDA in the absence of an order under 35 U.S.C. § 271(e)(4)(A), the district court amended the judgment to include such an order, and revised the marketing injunction so that it ends on March 25, 2007, the date that the '303 patent expired. The district court thus clearly intended pediatric exclusivity to be applied against Mylan's ANDA. The FDA, however, delayed rescinding Mylan's approval because of Mylan's stay motion before this Court.

This Court's March 23, 2007 Order

On March 23, 2007, this Court issued an Order directing the parties to supply additional information relating to Mylan's stay motion: specifically how the *Apotex* Decision affects Pfizer's pediatric exclusivity and the FDA's approval of Mylan's ANDA. The Court clearly intended to preserve the *status quo* pending its decision on the stay. Thus, the Court held in abeyance Mylan's stay motion and it *temporarily* stayed the district court's order pending the Court's consideration of the parties' further submissions.

Events Subsequent To This Court's March 23, 2007 Order

Pfizer received the Court's March 23, 2007 Order at 12:02 PM. About an hour later, Mylan irrevocably altered the *status quo*. Relying on the temporary stay issued by this Court, Mylan announced that it had launched its generic version of Norvasc®, and thereby triggered its 180-day exclusivity under the Hatch-Waxman statute. 21 U.S.C. 355(j)(5)(B)(iv). Thus, Mylan used the temporary stay provision, which clearly was intended to preserve the *status quo* pending further consideration of these supplemental briefs, to irrevocably alter the *status quo* by launching its product onto the commercial market.

Pfizer has been irreparably injured by Mylan's launch. Regardless of what action this Court, or any other court takes in the future, Pfizer will lose substantial sales of Norvasc® to Mylan's generic product, and Pfizer has no legal

remedy to recover its losses. Additionally, Pfizer will lose at least some of the six-month pediatric exclusivity period. At approximately 5:00 pm on March 23, 2007, Pfizer announced that in response to Mylan's launch, Pfizer had launched its own generic version of Norvasc®. Pfizer was forced to launch by Mylan's premature action in an attempt to mitigate its sales losses as Mylan sought to flood the supply channels.

ARGUMENT

I. How The FDA Applies Pediatric Exclusivity

Pediatric exclusivity operates as an extension of the data, market, and patent exclusivities that apply to innovative products under provisions of the Hatch-Waxman law. *See generally* 21 U.S.C. § 355a(c)(1) & (2); 35 U.S.C. § 271(e)(2)(A). Pediatric exclusivity attaches at the end of a patent term, and adds six months to the statutory restrictions against FDA approval of ANDAs. *See generally* 21 U.S.C. § 355a. Thus, with respect to Pfizer's '303 patent, which expired on March 25, 2007, the term of pediatric exclusivity runs until September 25, 2007.

Because the statutory restrictions of FDA approval for ANDAs operate individually against each ANDA, pediatric exclusivity also operates individually against each ANDA. Thus, the effect of this Court's *Apotex* Decision must be considered individually against each ANDA. Although individual

circumstances will determine how this works, the nine amlodipine besylate ANDAs of which Pfizer is aware can be divided into two groups, as described below. If not for the stay this Court issued on March 23, Pfizer believes that all of these ANDAs would be subject to pediatric exclusivity at this time.

a. One group of ANDAs includes those that did not challenge the '303 patent. These ANDAs are subject to pediatric exclusivity pursuant to 21 U.S.C. § 355a(c)(2)(A). The FDA cannot approve these ANDAs unless and until their sponsors challenge the '303 patent and obtain court orders holding the '303 patent invalid or not infringed.

b. The other group of ANDAs consists of those that challenged the '303 patent; were held to infringe the '303 patent and were thus subject to an order under 35 U.S.C. § 271(e)(4)(A) requiring that their approval not be made effective before expiration of the '303 patent. This group included Mylan's ANDA, until this Court issued the temporary stay on March 23, 2007, and also includes the Apotex ANDA. The FDA cannot approve these ANDAs so long as they are subject to orders under 35 U.S.C. § 271(e)(4)(A). As demonstrated below, the *Apotex* Decision that issued last Thursday did not, in and of itself, modify or reverse any orders under 35 U.S.C. § 271(e)(4)(A). Thus, Pfizer's position is that the FDA cannot

approve any of these ANDAs. The Mylan ANDA holds full FDA approval, notwithstanding the district court order under 35 U.S.C. § 271(e)(4)(A) that required FDA to rescind its approval, only because of the temporary stay that this Court issued on March 23, 2007.

II. The *Apotex* Decision Did Not Immunize Any ANDA From Pediatric Exclusivity

The *Apotex* Decision is not final and has no legal effect unless and until this Court issues a mandate implementing the decision. No mandate may issue until the later of seven days following expiration of the time for filing a petition for rehearing, or seven days following disposition of such petition. Fed. R. App. P. 41(b).[2]

Unless and until a mandate issues, Pfizer's position is that the FDA should not give effect to the *Apotex D*ecision by altering the approval status of any ANDA, including Apotex's. The FDA's own regulations and guidances support Pfizer's position. FDA guidance on ANDA approvals clearly states that, when a district court's decision of patent infringement in Paragraph IV ANDA

[2] Pfizer has 14 days following this Court's filing of the decision to file a petition for rehearing. Fed. R. App. P. 40(a). Pfizer will file a petition for rehearing within the 14-day period, and it is making every effort to do so as soon as possible. Issuance of a mandate in the *Apotex* case will be automatically stayed when Pfizer files its petition for rehearing. Fed. R. App. P. 41(d)(1).

litigation is reversed on appeal, the agency cannot approve the pending ANDA until "the date the district court issues a judgment that the patent is invalid, unenforceable, or not infringed *pursuant to a mandate issued by a court of appeals*." *See* FDA Guidance For Industry, Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, ¶ IV(A) (Mar. 2000) (emphasis added); available at http://www.fda.gov/cder/guidance/3659fnl.pdf. FDA regulations regarding ANDA approvals also recognize the importance of avoiding premature agency actions based on judgments that are not final. The regulations require an ANDA applicant to notify the FDA of a "final judgment" in patent litigation, 21 C.F.R. § 314.107(e), and they establish an ANDA's approval date based on "the date the court enters judgment," 21 C.F.R. § 314.107(b)(3)(ii).

Even assuming *arguendo* that the FDA were inclined to act on the *Apotex* Decision, the decision has no direct effect on Mylan's approval status. Only an order in the *Mylan* action can affect Mylan's approval status. Indeed, until this Court entered its temporary stay, the FDA had expressed its intention to withdraw its final approval of Mylan's ANDA, even though Mylan had brought the *Apotex* Decision to the FDA's attention.

III. If This Court's Temporary Stay Is Lifted, The FDA Should Implement Pfizer's Six-Month Period Of Pediatric Exclusivity As to Mylan

The '303 patent expired at midnight on Sunday, March 25, 2007. Neither that event, nor this Court's issuance of the temporary stay on March 23, 2007 moots this case. Both this Court and the FDA may enter orders that implement Pfizer's pediatric exclusivity. If this Court lifts its temporary stay, the § 271(e)(4)(A) order in the Amended Judgment will have full force and effect, even though the stay will have been lifted after the '303 patent expired.

As we described in Pfizer's Response to Mylan's stay motion (Pfizer Response at p. 12), ALZA's patent in the fentanyl case expired while Mylan's appeal from the patent judgment was pending in this Court. By exercising jurisdiction over the appeal, this Court concluded that the § 271(e)(4)(A) order from which Mylan appealed had potential effect after patent expiration. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1368 (Fed. Cir. 2004). Had the Court read the § 271(e)(4)(A) order as having no effect after the patent expired, then it would have been required to dismiss Mylan's appeal as moot.

Here, the § 271(e)(4)(A) order was entered on March 16, 2007, before the '303 patent expired. The temporary stay that this Court entered does not render the § 271(e)(4)(A) order moot, even though the temporary stay was in effect when the '303 patent expired. Once the temporary stay is lifted, the § 271(e)(4)(A) order in this case requires that the FDA set an effective approval

date "not earlier" than the patent expiration. As explained in *Mylan Labs., Inc. v. Thompson,* 389 F.3d 1272 (D.C. Cir. 2004), the result of such an order is that the ANDA is subject to pediatric exclusivity.

IV. Pfizer Has Compelling Grounds For Rehearing

Pfizer's arguments for rehearing and rehearing *en banc* are substantial. The district court in *Apotex* was the first of three different district courts to hold that the '303 patent was valid and not obvious. Both other district court judges held that the ANDA filers, including Mylan, had failed to prove prima facie obviousness.

The Panel decision is in conflict with the well-established law holding that an invention is not obvious (even if it were prima facie obvious) if the claimed invention has at least one unexpected property that is superior to the closest prior art. *In re Papesch,* 315 F.2d 381 (CCPA 1963); *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); *In Re Neave,* 370 F.2d 961 (C.C.P.A. 1967); *In re Ackermann*, 444 F.2d 1172 (C.C.P.A. 1971).

The *Apotex* district court found that the amlodpine besylate salt was not obvious based on substantial evidence that amlodipine besylate's properties are unexpectedly superior to the prior art: (a) the properties of new salts are entirely unpredictable (the properties of salts of different active compounds using a particular anion teach nothing about the properties of a new salt made with the

same anion and a new active compound); (b) both the stability and processing properties of amlodipine besylate are superior to the prior art and amlodipine besylate has a superior combination of all properties that no other amlodipine salt has; and (c) the advantages of the amlodipine besylate salt compared to the prior art are substantial. The amlodipine besylate tablets unexpectedly allow the use of a preferred and cost effective manufacturing procedure which the prior art salt of amlodipine did not. The stability of amlodipine besylate unexpectedly is greatly improved, reducing degradants that could have threatened approval of the drug and permitting a superior shelf-life of the product. None of these findings is clearly erroneous.

The Panel improperly rejected the district court's findings of fact in violation of Fed. R. Civ. Pro. 52, and contravened well-established precedent by this Circuit by relying heavily on the inventor's own mental processes and his own non-public research to establish obviousness. By rejecting the invention as a product of routine experimentation, the Panel decision conflicts with the express provisions of 35 U.S.C. § 103 and contravenes a long line of prior decisions of this Court that a trial and error method of making an invention does not undermine patentability.

V. To Prevent Further Irreparable Injury To Pfizer, This Court Should Lift Its Stay Forthwith And Permit Pediatric Exclusivity To Become Effective

Pfizer's injury resulting from Mylan's unilateral destruction of the *status quo* is irreparable. Sales of Norvasc® in the United States alone last year were approximately $2.5 billion. Based on prior generic drug maker entries, Pfizer can expect that it will lose more than 98% of its Norvasc® sales during the first full year that Mylan's generic product is on the market. The monetary value of the full pediatric exclusivity period, based on 2006 sales, is approximately $1 billion. The enormous financial losses that Pfizer will suffer are irreparable. They cannot be remedied by monetary relief, because Pfizer has no clear damages remedy. Its pediatric exclusivity is not a property right created by the Patent Act. It is a right created by the Food, Drug and Cosmetic Act, which confers no private right of action -- and certainly provides no avenue for a private party to obtain monetary damages. *Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 986 (Fed. Cir. 2006).

Furthermore, the duration of pediatric exclusivity is limited -- six months. Every day during which Pfizer is unable to benefit from that exclusivity is a day that it never can regain.

The public interest militates in favor of implementing and maintaining pediatric exclusivity at least until the validity of the *Apotex* Decision

is assessed by this Court through rehearing. The FDA has recognized that pediatric exclusivity is an extremely important incentive that greatly benefits the public health.[3] This Court should not take any action in derogation of pediatric exclusivity unless and until it has determined with finality, after a full and fair rehearing process, that the patent supporting the exclusivity is invalid.

Finally, the balance of equities should be struck in Pfizer's favor. By launching its generic Norvasc® product based on this Court's temporary stay, entered with the clear intent to preserve the *status quo*, Mylan unilaterally destroyed the *status quo*. Having done so, Mylan deserves no further protection by this Court's temporary stay.

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[3] In 2001, the FDA advised Congress that the "pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date." *See* S. Rep. No. 107-79, Best Pharmaceuticals for Children Act, at 5.

CONCLUSION

Pfizer's injury resulting from Mylan's launch of its generic Norvasc® tablets on Friday is both severe and irreparable. Its need for relief from this Court is urgent. Consequently, Pfizer respectfully requests that this Court lift its temporary stay forthwith, thereby reinstating the district court's § 271(e)(4)(A) order. Once the order has been reinstated, based on the FDA's rulings in the fentanyl cases, the FDA, pursuant to the § 271(e)(4)(A) order, is expected to implement Pfizer's six-month pediatric exclusivity period. Pfizer promptly will move for panel rehearing and rehearing *en banc* of the *Apotex* Decision. If Pfizer's petition is granted and the *Apotex* Decision is reversed, the Court, by permitting pediatric exclusivity to attach, will have limited the extent of Pfizer's irreparable injury. If its petition is denied, Mylan promptly can reenter the market at that time.

Dated: March 26, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I caused two copies of **RESPONSE OF PLAINTIFF–APPELLEE PFIZER INC. PURSUANT TO THE COURT'S MARCH 23, 2007 ORDER** to be served by Federal Express on the 26th day of March, 2007 upon the following:

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