IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC., AND MYLAN PHARMACEUTICALS INC.,

Plaintiffs,

and

MUTUAL PHARMACEUTICAL CO.,

Intervenor-Plaintiff,

v.

MICHAEL O. LEAVITT, et al.,

Defendants, Cross-Defendants

and

TEVA PHARMACEUTICALS USA, INC.,

Intervenor-Defendant

and

APOTEX INC.,

Intervenor-Defendant,Cross claimant

Civil Action No. 07-579 (RMU)

Judge Ricardo M. Urbina

APOTEX'S REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I. APOTEX IS ENTITLED TO A PRELIMINARY INJUNCTION TO COMPEL IMMEDIATE FINAL APPROVAL OF ITS OWN ANDA

A. Apotex Is Likely To Succeed On The Merits Because The Applicable Courts Find The Federal Circuit Judgment Of March 22, 2007 To Be A Determination

Contrary to the FDA's position, both the Federal Circuit and the Northern District of Illinois view the Federal Circuit's March 22, 2007 judgment in *Pfizer v. Apotex* as a court determination worthy of affording legal effect. The Federal Circuit itself gave effect to its March 22, 2007 judgment in granting Mylan a stay of injunction in its district court proceeding. Order, *Pfizer v. Mylan Laboratories,* No. 2007-1194 (Fed. Cir. March 23, 2007) (attached as Exhibit A). In granting Mylan its relief, the Federal Circuit defined its March 22, 2007 judgment as an "invalidity **determination**" stating:

> Pfizer and Mylan are each are directed to respond, no later than 10 a.m. on Monday, March 26, 2007, concerning how ***the invalidity determination*** affects the pediatric exclusivity period and the ANDA approval. Inter alia, the parties should address when and how the FDA will likely respond to the court's decision in no. 2006-1261. Each response should not exceed 15 pages.

The FDA's view that the Federal Circuit's judgment of invalidity was not a court determination is arbitrary, capricious and not in accordance with law. The FDA knew that the Federal Circuit characterized its own action as a "determination." The FDA also knew that the Federal Circuit relied on the March 22, 2007 judgment to give relief to a third party (Mylan) prior to patent expiration based on its determination. The FDA recognized the stay in acquiescing to Mylan's entry into the market for generic amlodipine besylate, but that stay was itself predicated on the March 22, 2007 judgment. Government Defendants' Combined Memorandum In Opposition To Motions For Injunctive Relief Filed By Teva, Apotex, and

Mylan, at 30 (hereinafter "FDA Mem."). Because the "stay" that the FDA recognized is itself dependant on the March 22, 2007 judgment on which it is predicated, the FDA is being arbitrary and capricious in giving Mylan the benefit of the judgment and not Apotex.

The FDA allowed Mylan to go to market on the strength of the "stay" of the injunction in the district court. That the FDA has not allowed Apotex to go to market with *its* stay of *its* district court injunction is also a reason that the FDA's decision in this matter is arbitrary, capricious and not in accordance with law. Unlike the FDA, the Northern District of Illinois gave effect to the Federal Circuit's determination and judgment that claims 1-3 of the Pfizer's patent were invalid. On March 29, 2007, the Northern District of Illinois ordered that its injunction against Apotex would be lifted on April 3, 2007 in view ***of the March 22, 2007 judgment, not patent expiration***. *See Order*, Pfizer v. Apotex No. 3-C-5289 (N.D. Ill. Mar. 29, 2007) (attached as Exhibit B).

The district court was correct in acting based on the Federal Circuit determination. The Federal Circuit opinion and judgment was precedental and unvacated as of March 22, 2007. The opinion is not a legally powerless document – it has precedental effect upon release unless vacated. *Vaicaitiene v. Partners in Care, Inc.*, 2005 U.S. Dist. LEXIS 13490 (D.N.Y. 2005) (observing that opinions are precedent, but may be vacated for mootness).

The actions of the Federal Circuit and the Northern District of Illinois comport with the standard legal definitions of "judgment" and "mandate." A "judgment" is "[a] court's final ***determination*** of the rights and obligations of the ***parties*** in a case." Black's Law Dictionary, at 856 (8th ed. 2004) (emphasis supplied) (attached as Exhibit C). A "mandate" is "[a]n ***order*** from ***an appellate court*** directing ***a lower court*** to take a specified action." *Id.* at 980 (emphasis supplied). It is the judgment that set forth the parties' rights and obligations, not the mandate.

Therefore, it is the judgment and opinion entered on March 22, 2007 by the Federal Circuit that meet the "court determines" language of the statute, not a mandate to be issued at some indeterminate point in the future. Both the Federal Circuit and the Northern District of Illinois were correct in acting on the determination of the March 22, 2007 judgment.

B. Apotex Is Likely To Succeed On The Merits Because Mylan And The FDA Have Not Rebutted Apotex's Arguments

The FDA and Mylan have failed to rebut Apotex's showing that the March 22, 2007 Federal Circuit judgment was a final "determination." In particular, neither the FDA nor Mylan has rebutted that:

(1) As of March 22, 2007, the judgment entered on March 22, 2007 was the type of determination required for a petition for certiorari to the Supreme Court under Supreme Court Rule 14. (Apotex's Memorandum of Points And Authorities In Support Of Its Motion For Preliminary Injunction, at 6. (hereinafter "Apotex Mem."). Therefore, the judgment was "effective" as to at least the Supreme Court.

(2) Under the Federal Rules of Appellate Procedure, opinions or judgments are not automatically vacated when further review is granted. Apotex Mem. at 6.

(3) The discretionary reviews that follow the judgment do not principally consider the merits of the case. Apotex Mem., at 6-7.

(4) The statutes that the FDA alleges demonstrate "ambiguity" in the term "determines" are inapposite. Apotex Mem., at 9-10.

(5) Rather than giving determinative effect to the Federal Circuit's opinion and judgment, FDA is giving Pfizer's petition for a rehearing the effect of "vacating" the Federal Circuit's opinion and judgment. Apotex Mem., at 9-10.

(6) The prospects of discretionary review are very low-percentage. Apotex Mem., at 10.

These factors alone support a decision by this Court to grant Apotex's motion for preliminary injunction. The Federal Circuit's March 22 opinion and judgment is the last "determination" of validity and infringement by a "court" that is certain or even likely to occur. At this time, there is no judicial power that is holding up final approval for Apotex, only Pfizer's pediatric exclusivity based on a patent that has been held invalid as to Apotex. Any other conclusion allows Pfizer to effectively make its own "determination" that the patent is valid and infringed binding on the FDA and Apotex by merely filing a petition for rehearing.

C. On March 22, 2007, "A Court Determine[d]" That Pfizer's Patent Was Invalid

The only proper question before the FDA is whether on March 22, 2007, the Federal Circuit (a "court") had "determined" that Pfizer's patent was invalid or not infringed vis-à-vis Apotex. 21 U.S.C. § 355a(c)(2)(B) ("the court determines"). The FDA is being arbitrary and capricious because it uses the direct results of the March 22, 2007 Judgment as a determination to permit Mylan to be on the market, and refuses to allow Apotex to be on the market from the same determination – a determination that Apotex had won, not Mylan.

The FDA's (and Mylan's) reliance on the commentary to Federal Rule of Appellate Procedure 41 does not overcome the fact that there was a "court" "determination" on March 22. For example, the commentary to Federal Rule of Appellate Procedure 41(d) shows that

"judgment" was addressed in the commentary for Federal Rule of Appellate Procedure 41(c) only in the context of the "suspending" the finality of the judgment. This has nothing to do with whether a judgment represents a court determination (which it does). This is also in line with Black's Law Dictionary, which defines "suspend" as "to interrupt, postpone, defer." Black's Law Dictionary, at 1487 (8th ed. 2004). Finally, this is also in line with *Hibbs v. Winn*, 542 U.S. 88, 97 (2004). In *Hibbs v Winn*, the Supreme Court noted: "That order, we conclude, *suspended* the judgment's finality under *§ 2101(c),* just as a timely filed rehearing petition would, or a court's appropriate decision to consider a late-filed rehearing petition" (emphasis added). One can only suspend something that already exists – therefore, there ***was*** a final determination as of March 22, 2007, and both the FDA and Mylan have so admitted.

Finally, the case law cited by Mylan and the FDA does not assist them because none of their authorities deal with the issue of whether a judgment ***was*** final before its finality was suspended, which it was. The fact that the Federal Circuit's March 22 judgment will not become final again until the discretionary procedures have run their course is immaterial.

II. APOTEX IS ENTITLED TO A PRELIMINARY INJUNCTION TO REQUIRE FDA TO ORDER MYLAN TO STOP MARKETING

Pursuant to 35 U.S.C. §271(e)(4)(A), the Pennsylvania district court's order automatically changed the status of Mylan's application from finally to tentatively approved. FDA and Mylan erroneously argue the Pennsylvania district court's order changing the effective date of approval of Mylan's application is ineffectual because FDA never got around to changing the effective date. FDA argues it was too busy litigating its authority to "convert" Mylan's final approval to a tentative approval in response to the district court's injunction, and that the matter became moot when the Federal Circuit stayed the district court's injunction. FDA's Mem. at 38.

Mylan argues its application is finally approved because once the Federal Circuit issued its stay, the FDA "properly refused to act to reset the effective date of Mylan's approval." Plaintiffs' Opposition to Apotex's Motion for Preliminary Injunction (hereinafter "Mylan's Opposition") at 11. FDA and Mylan fail to acknowledge that, pursuant to 35 U.S.C. § 271(e)(4)(A), the Pennsylvania district court's decision did not require any FDA action to change the status of Mylan's approval; rather Mylan's final approval was converted to a tentative approval by operation of law.

The effective date of an approval following a finding of infringement by a district court is governed by the patent laws, **not** the FDC Act. While FDA is entrusted to interpret and enforce the provisions of Hatch-Waxman, *Mylan v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004) ("*Mylan (fentanyl*)"), FDA is not entrusted with interpreting any provision of the patent statute and its interpretations are due no deference. *Id.* at fn. 5 ("Mylan also asserts, correctly, that the court owes no deference to the FDA's interpretation of 35 U.S.C. Section 271(e)(4)(A), a patent statute provision which the FDA is not charged with administering.") In *Mylan (fentanyl)* the D.C. Circuit interpreted the Patent Statute, 271(e)(4)(A), and held the district court – **not** FDA – delayed the approval of an application after a finding of infringement. FDA is now bound by that decision.

Despite the D.C. Circuit's ruling, FDA now argues *Mylan (fentanyl)* supports its position that FDA action is required to convert the final approval to tentative approval. FDA's arguments are not based on the interpretation of any law, but rather a misinterpretation of the D.C. Circuit's *Mylan (fentanyl)* decision. FDA argues that "in *Mylan (fentanyl)* the D.C. Circuit noted that some action was required by FDA to convert a final approval to a tentative approval: 'Mylan contends that FDA lacked authority *to revoke* Mylan's final ANDA approval…,' 'the provision

does not prohibit FDA from *withdrawing* approval…'" FDA Mem., p. 39 (emphasis in original). FDA proffers Mylan's arguments in *Mylan (fentanyl)* to support its position.

FDA's quotation of Mylan's arguments and its representation of those arguments as "notations" by the D.C. Circuit that some FDA action is required to "revoke" or "withdraw" final approval is directly contrary to the D.C. Circuit's actual holding in that case. The D.C. Circuit explicitly rejected the very interpretation FDA (and Mylan) are trying to advocate here:

> We are skeptical whether the parties properly characterize the FDA's action as "withdrawal" or "revocation" of approval. It seems to us that Mylan's ANDA approval was never in fact "withdrawn" or "revoked" but remained continuously in effect based on the FDA's review of the ANDA described in the November 21, 2003 final approval letter. The approval merely underwent a change of status or classification from final to tentative **after the Vermont district court delayed its effective date**.

389 F.3d at 1282 fn. 8 (emphasis added). The D.C. Circuit (contrary to FDA's assertion) interpreted the Patent Statute to mean an order of the district court, not any action by FDA, changed the status of Mylan's application. FDA's attempt to elevate previously rejected arguments of Mylan to the status of a notation by the D.C. Circuit court that FDA, not the district court, must change the status of an ANDA approval in this circumstance, demonstrates FDA's decision is arbitrary and capricious and wrong as a matter of law.

FDA's argument also is not supported by its own letter ruling in *Mylan (fentanyl)*, where it found the Vermont district court's order, and not FDA action, changed the status of Mylan's approval. *Id.* at 1277 ("…the Vermont district court's order … ***transformed*** Mylan's ANDA

approval into 'an approval with a delayed effective date,' which 'is a tentative approval that cannot be made effective until FDA issues a letter granting final effective approval'" (emphasis added)).[1] The D.C. Circuit upheld the FDA's letter ruling finding "the patent remedy statute directs that upon a finding of infringement **the district court establish** a new effective date for approval …" *Id.* 1282 (emphasis added). After that happened, according to FDA's own regulations it was necessary to issue a second letter granting final approval of Mylan's ANDA application at an appropriate date in the future that was no earlier than the expiration date of the subject patents.[2] *See* Apotex Mem. at 16-18 and authorities cited. The FDA and Mylan do not counter these arguments.

Mylan's filing suit in this Court to prevent FDA from doing something that happened automatically when the Pennsylvania district court issued its order is irrelevant to the issue. First, Mylan's efforts to enjoin the FDA constitutes an improper use of this Court to subvert a binding ruling of the Pennsylvania district court. Both in *Mylan (fentanyl)* and *Ortho-McNeil v. Mylan*, 2007 WL869545, (March 20, 2007), Mylan was told that there was absolutely no basis for Mylan's arguments that the FDA had any choice but to obey the patent court (*Ortho-McNeil* was decided a mere three days prior to Mylan requesting an injunction in this Court). Mylan was

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[1] FDA later argued to the D.C. Circuit that it could withdraw approval following a §271(e)(4)(A) order; as noted above the Court rejected that premise.

[2] That FDA issues a letter informing an applicant of the status of its ANDA is of no importance *vis a vis* the district court's order. Once the district court states the effective date of the application is no earlier than the date of patent expiry, the approval is delayed by operation of law. FDA's later letters simply constitute housekeeping. FDA's second letter to Mylan in *Mylan (fentanyl)* says as much. *Id.* at 1278 (the second letter "again noted that, after the Vermont district court's order, Mylan's ANDA approval had a "delayed effective date," which, by FDA regulation, constitutes 'tentative' rather than 'final' approval").

told this because the patent court, not the FDA, determines the earliest effective date for final ANDA approval following a finding of infringement. In *Mylan (fentanyl)*, the D.C. Circuit explicitly held the FDA was not charged with interpreting the ruling of the Vermont district court setting the earliest effective date of Mylan's approval, and that the order was unambiguous. 389 F.3d at 1279 fn. 5 (the Court held the Vermont district court's decision stating that "the effective date of any approval of Mylan's ANDA product shall be no earlier than the date of expiration of the '580 patent family", *id.* at 1277, "presented [no] ambiguity" that would require interpretation from the FDA.)

Second, the New Jersey district court criticized Mylan for arguing Hatch-Waxman governed the district court's order under 271(e)(4)(A). *Ortho-McNeil* at *2 ("Mylan asserts that Section 355(j) limits its Section 271(e)(4)(A) relief.… Section 355(j)(5) does not concern the authority of the district court; it limits neither the availability of remedies under Section 271(e)(4)(A), nor the authority of the district court.") The *Ortho-McNeil* court found Congress intended "that the ***district court change*** the effective date." *Id.* (emphasis added). That court dismissed Mylan's claims stating that it (not FDA) "will delay the effective date of the ANDAs pursuant to 35 U.S.C. Section 271(e)(4)(A)." *Id.*

Taken together, these rulings demonstrate that once the Pennsylvania district court ordered Mylan's approval date delayed under § 271(e)(4)(A), there was no basis for Mylan to seek ***any*** remedy from FDA. Mylan sought an injunction against FDA from this Court anyway. Mylan's attempt to enjoin the FDA was nothing more than a use of the courts of the United States to subvert a valid and binding order of the Pennsylvania district court by obtaining an injunction against FDA forcing it to ignore a binding judgment that had already changed the

status of Mylan's approval. That suit has no bearing on the issues presently before the Court. This point is lost on FDA, if not Mylan.

Contrary to Mylan's argument that "[i]mprovident action by the FDA would have rendered the Federal Circuit's stay meaningless," Mylan Mem. at p. 12, the Federal Circuit's stay simply allowed FDA to proceed under its established regulations to consider whether it was appropriate to re-issue final approval to allow Mylan to sell. Pursuant to FDA's regulations, Mylan could only obtain final approval (following conversion to tentative approval) when FDA issued a letter granting it a right to sell its generic. 21 C.F.R. § 314.107(b)(3); *see, Barr Labs. v. Thompson*, 238 F.Supp.2d 236, 245-50 (D.D.C. 2002).

FDA is also incorrect to suggest that once the Federal Circuit stayed the order, the approval was magically converted back to a final approval. As previously stated, the Federal Circuit ruling simply put the ball back in the FDA's court to decide how to proceed given the status of Mylan's case. Had FDA considered the issue, it could have solicited comments from all the interested parties and prevented the irreparable harm that is currently being caused Apotex. It also could have allowed all the parties to be hear ***prior*** to its decision whether to grant any generic final approval. Indeed, had it considered the issue it would have found that Mylan could not be given final approval because Mylan did not have a court judgment finding Pfizer's patent invalid and non-infringed. Therefore, under FDA's own interpretation of Hatch-Waxman, when the patent expired, Mylan's ANDA certification was converted to a Paragraph II certification and Mylan was barred by Pfizer's pediatric exclusivity.

It is unclear why it offends the FDA to have Mylan caught in FDA's procedural snafu but not Apotex. In fact, FDA failed to justify its decision to treat the decision of the Pennsylvania district court in Mylan's case as if it never happened, yet to treat the Illinois district court order

in Apotex's case as the only decision that matters. FDA's inexplicable but overt favoring of Mylan demonstrates its rulings are arbitrary, capricious, and entitled to no deference.

III. THE FDA AND MYLAN HAVE FAILED TO COUNTER APOTEX'S STATEMENTS AND ARGUMENTS ON IRREPARABLE HARM

Mylan failed to negate Apotex's claim that it could obtain 30% market share if it enters the market soon, but only a 10% market share if it does not enter the market soon, *see* Apotex Mem., at 12, other than labeling Apotex's statements as speculative. The only thing that all of the industry parties agree on is that each party views not being in the market as irreparable harm. (The only party alleging that it is not irreparable harm is the FDA, which is not a market participant, and is not positioned to evaluate whether the harm is irreparable or not.)

Moreover, Apotex provided authority for the proposition that loss of market share in highly competitive industries where the market share is unlikely to be recovered is irreparable harm. Apotex Mem. at 21, *citing Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 595-96 (3d Cir. 2002). Neither Mylan nor the FDA has provided directly contrary appellate authority.

CONCLUSION

For the reasons given above, the Court should grant Apotex's motion for a preliminary injunction.

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Respectfully submitted,
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