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 ITS MOTION FOR RECONSIDERATION

INTRODUCTION

Apotex is entitled to immediate final approval of its ANDA. The Northern District of Illinois vacated its injunction that prevented FDA from approving Apotex's ANDA. Because the Illinois district court injunction was lifted, FDA does not have any reason to withhold immediate approval of Apotex's ANDA that is not arbitrary, capricious or not in accordance with law. In its response, FDA attempts to reconcile its disparate treatment of the effect of the lifting of the injunctions against Apotex and Mylan in view of this Court's April 30, 2007 Memorandum

Opinion and Order (Dkt. 67) ("Mem. Op.") at 13-14. But the fact remains that FDA has let Mylan go to market on the strength of the stay of the Pennsylvania district court's injunction against Mylan, yet has refused to grant Apotex's final approval, even though Apotex has both a judgment from the Federal Circuit that the asserted claims of Pfizer's '303 patent are invalid ***and*** an order from the district court lifting its injunction against final FDA approval for Apotex's ANDA. FDA is therefore arbitrarily engaging in disparate treatment of Mylan and Apotex. Accordingly, the Court should reconsider its denial of Apotex's motion for preliminary injunction, grant it, and order FDA to immediately grant final approval to Apotex's ANDA for amlodipine besylate.

ARGUMENT

I. FDA HAS PROFERRED INCONSISTENT EXPLANATIONS

Under this Court's ruling in the present case, a district court decision that the relevant patent is valid and infringed triggers entitlement to pediatric exclusivity; that district court decision is binding on FDA unless it is ***stayed*** or mandate issues overturning the judgment. Here, the district court injunction against final approval for Apotex's ANDA was lifted by the issuing district court following the Federal Circuit's judgment that the asserted claims of Pfizer's '303 patent were invalid and therefore could not be infringed by Apotex. As this Court stated in its denial of all motions for preliminary injunction:

> On January 24, 2006, the district court issued a ruling in which it determined that Pfizer's patent was valid and would be infringed. *Pfizer, Inc. v. Apotex, Inc.*, No. 03-5289, 2006 U.S. Dist. LEXIS 95778 (N.D. Ill. Jan. 24, 2006). This ruling triggers the plain text pronouncement in the statute entitling Pfizer to pediatric exclusivity. 21 U.S.C. § 355a(c)(2)(B). Moreover, the district court's ruling is effective and remains so during the pendency of the appeal ***unless the district court's judgment is stayed*** (either by the district court itself or the appellate court), Fed. R. App. P. 8, or until the Federal Circuit issues its mandate, *Deering Milliken, Inc.*

> *v. F.T.C.*, 647 F.2d 1124 (D.C. Cir. 1978). "[T]he vitality of [the district court] judgment is undiminished by pendency of the appeal. ***Unless a stay is granted either by the court rendering the judgment*** or by the court to which the appeal is taken, the judgment remains operative." *Id.* Therefore, ***the pediatric exclusivity period, triggered by the district court's ruling, remains effective until it is formally stayed*** or reversed.

Mem. Op. at 13-14 (emphasis supplied). Under the plain language of this Court's Opinion, Apotex should not be subject to pediatric exclusivity at this time because the Illinois district court judgment against Apotex that triggered pediatric exclusivity has now been lifted.

FDA's ***latest*** position is an attempt to ***distinguish*** this Court's decision:

> FDA never stated expressly or implied that where district court determined that an ANDA applicant, such as Apotex, infringed a valid patent, enjoined the applicant from marketing, and subsequently lifted that injunction, the lifting of the injunction, by itself, would constitute an affirmative court determination of patent invalidity such that pediatric exclusivity would no longer bar final approval.

Letter from Gary J. Buehler, Director, Office of Generic Drugs, to Kiran Krishnan, U.S. Agent for Apotex Inc., at 3-4 (May 7, 2007) ("May 7 Decision Letter") (Dkt. 71-2).

FDA also proffered the following explanation for why, in its opinion, the stay of the Illinois district court's injunction against Apotex does not entitle Apotex to immediate final approval:

> Either the Illinois district court's original judgment that the patent is valid and infringed remains in effect until the mandate issues, or, at best, the lifting of the injunction nullified that court's initial decision so that there is in effect no district court judgment. Under either scenario, Apotex has not obtained a final effective court determination that the patent is invalid such that pediatric exclusivity has ceased to bar approval of Apotex's ANDA.

May 7 Decision Letter at 3.

However, in making those statements, the FDA has ignored the ***different*** position proffered in its decision letter of April 18, 2007. There, in discussing Mylan's situation, FDA stated that the Federal Circuit's stay of the Pennsylvania district court's injunction against Mylan meant that FDA had "no basis" to deny Mylan final approval status. *See* letter from Gary J. Buehler, Director, Office of Generic Drugs, to ANDA Holder/Applicant for Amlodipine Besylate Tablets, at 5 n. 4 (Apr. 18, 2007) ("April 18 Decision Letter") (Dkt. 40) (discussed in Apotex's Memorandum In Support Of Emergency Motion For Reconsideration (Dkt. 68) at 4-6). Thus, FDA has changed its positions without offering any rational explanation. This is unlawful under the Administrative Procedure Act. *See Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Company*, 463 U.S. 29, 57 (1983) ("an agency changing its course must supply a reasoned analysis"); *Amax Land Company v. Quarterman*, 181 F.3d 1356, 1365 (D.C. Cir. 1999) (same, *citing State Farm*). It also fails for "want of reasoned decisionmaking." *See Teva Pharmaceuticals, U.S.A., Inc. v. FDA*, 441 F.3d 1, 4 (D.C. Cir. 2006).

II. THE FDA'S CURRENT "FINAL EFFECTIVE DECISION" RULE IS ARBITRARY AND CAPRICIOUS IN APPLICATION AS IT RESULTED IN THE UNLAWFUL DISPARATE TREATMENT OF APOTEX AND MYLAN

FDA denied Apotex's application for immediate approval because, in its view, "[t]he March 29 Order is not a final effective decision that the patent is invalid or not infringed." Government Defendants' Opposition To Motions For Reconsideration Filed By Apotex And Mylan (Dkt. 71), at 2, quoting May 7 Decision Letter at 3. Specifically, FDA rejected Apotex's view, set forth in a May 1, 2007 letter to the agency (Dkt. 68-3), that the judgment of the Federal Circuit in *Pfizer v. Apotex* that Pfizer's patent is invalid, combined with the Illinois district court's April 3, 2007 lifting of its injunction that ordered the effective date of Apotex's ANDA approval be delayed, requires that Apotex receive immediate final ANDA approval.

FDA asserts that there are differences between Apotex's situation and Mylan's situation, but these purported distinctions do not hold water. FDA has allowed Mylan to go to market without "a final effective decision that the patent is invalid or not infringed," from either the district court or the Court of Appeals. May 7 Decision Letter at 3.

FDA has permitted Mylan to bypass pediatric exclusivity on the strength of a stay of the district court's injunction against Mylan, and it must permit Apotex to do the same. On March 16, 2007, the Pennsylvania district court ordered that Mylan's ANDA approval date be not earlier than the expiration of the patent on March 25, 2007. Amended Judgment, *Pfizer, Inc. v. Mylan Laboratories, Inc.*, No. 02-cv-1628 (W.D. Pa. Mar. 16, 2007) (attached as Exhibit A). However, on March 23, 2007, the Federal Circuit, on the strength of the Federal Circuit's judgment that the asserted claims of Pfizer's '303 patent were invalid, stayed that injunction. Order, *Pfizer, Inc. v. Mylan Laboratories, Inc.*, No. 2007-1194 (Fed. Cir. Mar. 23, 2007) (attached as Exhibit B). In the view of the FDA, this warranted allowing Mylan to retain its final approval, despite the fact that Pfizer still had a final judgment against Mylan that Mylan infringed the '303 patent and that the '303 patent was valid. Importantly, the Federal Circuit did not enter a judgment in Mylan's favor, did not vacate the district court judgment, and did not issue a mandate in favor of Mylan. *See* Exhibit B.

Accordingly, Apotex and Mylan are similarly situated. Like Mylan, Apotex is entitled to final approval. At one point, like Mylan, Apotex did have a district court judgment against it and an injunction ordering that the effective date of any approval be delayed to a date no earlier than March 25, 2007. But like Mylan, Apotex's injunction has been lifted or stayed.

Under the reasoning articulated in this Court's April 30, 2007 decision, the Illinois district court's decision to lift its injunction against Apotex should be controlling here, as is

shown by the following language from the D.C. Circuit in *Deering Milliken, Inc. v. F.T.C.*, 647 F.2d 1124 (D.C. Cir. 1978):

> [T]he vitality of [the district court] judgment is undiminished by pendency of the appeal. Unless a stay is granted either by the court rendering the judgment or by the court to which the appeal is taken, the judgment remains operative.

That language was relied upon by this Court in its decision, Mem. Op. at 13-14. By failing to give effect to the district court order lifting its injunction against Apotex, FDA is taking an extreme, arbitrary position. Given that Apotex now has both a judgment in its favor from the Federal Circuit and a lifting of the district court injunction, it is entitled to final approval.

CONCLUSION

Apotex asks the Court to grant Apotex's motion for a preliminary injunction, and order FDA to immediately approve Apotex's ANDA for amlodipine besylate.

Respectfully submitted,

May 9, 2007

/s/Arthur Y. Tsien

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