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 EMERGENCY MOTION FOR RECONSIDERATION OF DENIAL OF ITS MOTION FOR PRELIMINARY INJUNCTION AND TO ESTABLISH AN EXPEDITED BRIEFING SCHEDULE

INTRODUCTION

Intervenor-defendant-cross claimant Apotex Inc. ("Apotex") respectfully seeks reconsideration of this Court's April 30, 2007 Memorandum Opinion and Order to the extent that this Court denied Apotex's motion for preliminary injunction to compel the Food and Drug Administration ("FDA") to immediately issue final approval of Apotex's ANDA for amlodipine

tablets. The basis for this motion for reconsideration is a critical fact of which FDA and this Court may not have been aware when they issued their decisions.

Because of the speed at which events have been taking place and the fact that Pfizer's six month pediatric exclusivity period will run out on September 25, 2007, Apotex respectfully requests that this Court establish an expedited briefing schedule on this motion for reconsideration. Specifically, Apotex proposes that any oppositions be filed by 12:00 noon on Monday, May 7, 2007, and that Apotex's reply be filed by 5:00 p.m. on Tuesday, May 8, 2007. Counsel for Apotex consulted with counsel for other parties regarding an expedited briefing schedule. Counsel for plaintiffs Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc., counsel for Mutual Pharmaceutical Co., and counsel for Teva Pharmaceuticals USA, Inc. do not object to this briefing schedule. Counsel for federal defendants proposed an alternative schedule, under which oppositions would be due by 12:00 noon on Tuesday, May 8, 2007, and Apotex's reply would be due by 5:00 p.m. on Wednesday, May 9, 2007.

A proposed order establishing Apotex's proposed expedited briefing schedule is attached.

May 3, 2007

Respectfully submitted,

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APOTEX INC.,

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Judge Ricardo M. Urbina

APOTEX'S MEMORANDUM IN SUPPORT OF EMERGENCY MOTION FOR RECONSIDERATION OF DENIAL OF ITS MOTION FOR PRELIMINARY INJUNCTION

INTRODUCTION

Apotex Inc. ("Apotex") seeks reconsideration of this Court's April 30, 2007 Memorandum Opinion and Order (Dkt. 67) ("Mem. Op.") denying Apotex's Application for Preliminary Injunction (Dkt. 47), in view of the fact that, in addition to being reversed by the Federal Circuit in *Pfizer v. Apotex*, the district court's judgment against Apotex was ***vacated*** by the district court in an Order dated March 29, 2007 (attached as Exhibit A). Under this Court's

ruling in the present case, a district court's decision is considered binding on FDA unless it is stayed or mandate issues overturning the judgment.

> 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 added).

In this case, Mylan obtained the benefit of a stay of the injunction against it, which FDA reasoned entitled Mylan to get to market. Apotex's case is actually more compelling to Mylan's because the underlying district court injunction in *Pfizer v. Apotex* was not just stayed, it was vacated by the issuing district court. Because the district court injunction in Apotex's case has been vacated, Apotex is entitled to the same benefit that Mylan has already received. *Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (stating that an agency must afford similar treatment to comparable cases). In other words, if a stay of the district court's injunction counts for Mylan, it must count for Apotex too under the logic of FDA's and this Court's decisions. As such, Apotex is entitled to an injunction to compel immediate final approval and entry to market, just like Mylan.

ARGUMENT

I. THIS COURT HAS JURISDICTION TO RECONSIDER ITS APRIL 30, 2007 MEMORANDUM OPINION AND ORDER

As a threshold matter, this Court has jurisdiction to reconsider its April 30 decision. *See Decatur Liquors, Inc. v. District of Columbia*, 2005 WL 607881 (D.D.C. March 16, 2005) at *2 ("Absent an appeal, a district court has complete power over its interlocutory orders. *Ideal Toy Corp. v. Sayco Doll Corp.*, 302 F.2d 623, 625 (2d Cir. 1962) (*citing John Simmons Co. v. Grier Bros.*, 258 U.S. 828 (1922))"). A district court retains "broad discretion to grant or deny a motion for reconsideration." *Cobell v. Norton*, 224 F.R.D. 266, 273 (D.D.C. 2004) (*citing Cobell v. Norton*, 226 F.Supp.2d 175, 177 (D.D.C. 2002), in turn *citing Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 233-34 (1995)). While the precise standard governing a motion for reconsideration of an interlocutory order under Rule 54(b)[1] is unsettled in the D.C. Circuit, courts have held that Rule 54(b) reconsideration may be granted "as justice requires." *Cobell*, 224 F.R.D. at 272 (citations omitted).

For the reasons discussed below, reconsideration is appropriate in this case.

II. ON RECONSIDERATION, BECAUSE OF THE LIFTING OF THE INJUNCTION AGAINST APOTEX BY THE ILLINOIS DISTRICT COURT, THIS COURT SHOULD GRANT APOTEX'S MOTION FOR PRELIMINARY INJUNCTION AND ORDER FDA TO IMMEDIATELY ISSUE FINAL ANDA APPROVAL TO APOTEX

In its April 30 decision, this Court concluded in relevant part that Apotex was not entitled to a preliminary injunction to compel immediate final approval of its amlodipine ANDA because Apotex has not demonstrated a substantial likelihood of success on the merits. Apotex seeks

[1] Rule 54(b) provides that an interlocutory order "is subject to revision at any time before the entry of judgment adjudicating all the claims and the rights and liabilities of all the parties."

reconsideration of this decision because it believes that the Court may not have appreciated that, like Mylan, Apotex has had its district court ***injunction lifted***.

In its April 30 decision, this Court upheld FDA's April 18, 2007 administrative decision, which in relevant part concluded that Apotex is not entitled to immediate final approval of its amlodipine ANDA. At the same time, FDA's April 18 decision concluded that Mylan retains final ANDA approval despite a district court judgment against Mylan in Mylan's patent case. FDA so concluded because the Federal Circuit had ***stayed*** the injunction issued by the United States District Court for the Western District of Pennsylvania against Mylan, which Federal Circuit stay was based on the Federal Circuit's March 22, 2007 judgment in favor of Apotex and against Pfizer. 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) (attached as Exhibit B). In all relevant respects, this is the ***identical*** situation that Apotex is in now.[2]

In discussing Apotex's situation in its April 18 decision, FDA suggested that a stay of the district court's decision against Apotex would be a basis for final approval of Apotex's ANDA. This is because FDA applies district court decisions unless they are stayed.

> In FDA's view, the phrase "the court determines" in section 355a(c)(2)(B), in the context of a federal court of appeals reversing a district court judgment, should be read as the date the mandate issues for several reasons. When the district court decides a patent issue, ***FDA applies that decision, unless it is stayed, in determining issues related to ANDA approval.***

[2] There are two differences that should not have any effect on the outcome. First, Apotex, not Mylan, was the actual winning party in the case that resulted in the March 22, 2007 Federal Circuit judgment that Pfizer's patent is invalid. Second, the Apotex judgment was ***vacated*** by the district court that issued the injunction, rather than ***stayed*** by the Federal Circuit. If anything, these differences tilt in favor of Apotex.

April 18 Decision Letter, at 7 (emphasis added). This analysis implies that the FDA is treating Apotex as if it were not the beneficiary of a stay. But Apotex has even more than a stay: effective April 3, 2007, the United States District Court for the Northern District of Illinois ***lifted*** its injunction against Apotex relating to the '303 patent. Ex. A. Apotex has asked FDA to reconsider in light of this fact, but to no avail.[3]

In its April 27, 2007 opposition to all preliminary injunction motions before this Court, FDA reiterated its position that it was powerless to convert Mylan's final approval to a tentative approval based on the Pennsylvania district court's order, pursuant to 35 U.S.C. § 271(e)(4), that Mylan's effective date of ANDA approval be delayed until patent expiration (March 25, 2007). FDA so reasoned because the Federal Circuit had stayed the Pennsylvania court's injunction. Government Defendants' Combined Memorandum In Opposition To Motions For Injunctive Relief Filed By Teva, Apotex, And Mylan, at 16 ("FDA Mem.") (Dkt. 52). FDA reiterated and continued to hew to this position later in its brief: "As FDA explained in its decision, in terms of the statutory scheme, when the district court decides a patent issue, FDA applies that decision, unless it is stayed, in determining issues related to ANDA approval. [April 18 Decision Letter] at 6." FDA Mem. at 24.

[3] FDA may have had the understanding that the injunction in the district court prevents the FDA from approving Apotex's ANDA. However, since April 3, 2007, Apotex has not been enjoined. Out of concern that FDA was not aware that the United States District Court for the Northern District of Illinois had lifted its injunction against Apotex relating to Pfizer's '303 patent effective April 3, 2007, Apotex wrote to FDA on May 1, 2007 and requested final approval. Letter from Welsh & Katz to Gary J. Buehler, May 1, 2007 (attached as Exhibit C; exhibits to letter omitted). Apotex raised the same points that serve as the basis for the present motion for reconsideration. Apotex requested a response by the close of business on May 2, 2007, and informed FDA that it would seek relief from this Court in the absence of a response. In the afternoon of May 2, 2007, FDA representatives informed Apotex counsel that the agency would not be taking any action that day. FDA has not responded otherwise to Apotex.

In its April 27, 2007 reply in support of its motion for preliminary injunction, Apotex stated, in relevant part:

> 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).

Apotex's Reply in Support of Motion for Preliminary Injunction (Dkt. 65) at 3 (emphasis added).

Nevertheless, this Court accepted FDA's arguments and upheld FDA's refusal to issue immediate final approval for Apotex's ANDA, stating:

> 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 added).

Apotex respectfully submits that reconsideration here is in the interest of justice. *Cobell*, 224 F.R.D. at 272. Under FDA's April 18 decision, Apotex is entitled to immediate final approval of its ANDA because the Illinois district court judgment against Apotex was not just stayed, it was outright ***vacated***. Since that injunction was ***vacated*** by the issuing district court, Apotex is entitled to final approval now. Such a result is consistent with FDA's treatment of

Mylan, as FDA concluded that Mylan could continue to retain its final approval because the Pennsylvania district court judgment against Mylan had been stayed. There is no meaningful difference between Mylan and Apotex in this regard.

FDA must treat similarly situated firms in the same manner. *See Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (stating that an agency must afford similar treatment to comparable cases); *El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. HHS*, 300 F. Supp. 2d 32, 42 (D.D.C. 2004) (finding HHS's denial of coverage was arbitrary and capricious due to agency's inconsistent treatment of similarly situated parties); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 27-28 (D.D.C. 1997) (granting injunctive relief based on FDA's disparate treatment of one product as a device and another product as a drug); *Bush-Quayle '92 Primary Comm. v. FEC*, 104 F.3d 448, 453 (D.C. Cir. 1997) (stating that should an agency change its course, it "must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored") (quoting *Greater Boston Tel. Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)); *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) (finding Treasury acted arbitrarily for not conforming its electronic benefits transfer policies to its existing regulations nor offering a "reasoned analysis" for the difference).

Reconsideration is appropriate because it appears that FDA, and henceforth this Court, may not have been aware that the Illinois district court's judgment against Apotex in patent litigation had been vacated as of April 3, 2007. Taking that fact into account, Apotex respectfully submits that this Court should reconsider its April 30 decision and conclude, upon reconsideration, that Apotex is entitled to a preliminary injunction to compel FDA to immediately approve its ANDA for amlodipine besylate. Justice requires this result because

Apotex has the "stay" – if not more – that both FDA and this Court have made a condition for immediate final approval.

CONCLUSION

For the reasons stated, this court should reconsider its April 30 decision denying Apotex's motion for a preliminary injunction to compel immediate final approval of its amlodipine ANDA and, upon reconsideration, should grant the requested relief.

May 3, 2007

Respectfully submitted,

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