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 OPPOSITION TO TEVA'S MOTION FOR A PRELIMINARY INJUNCTION

INTRODUCTION

Teva Pharmaceuticals USA, Inc. ("Teva") is not entitled to an injunction ordering the United States Food and Drug Administration's ("FDA") to approve Teva's Abbreviated New Drug Application ("ANDA") for generic amlodipine. The injunction is inappropriate because:

- Teva does not have a substantial likelihood of success on the merits because the FDA's decision that Teva's ANDA is subject to Pfizer's pediatric exclusivity is not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A).
- Apotex will suffer irreparable harm if Teva is permitted to enter the market for amlodipine immediately.
- The public interest is in the faithful application of the laws.
- The balance of harms is neutral.

ARGUMENT

I. TEVA DOES NOT MEET THE STANDARD FOR A PRELIMINARY INJUNCTION

Teva's motion for preliminary injunction should be denied because it failed to satisfy the requisite four factors:

(1) a substantial likelihood of success on the merits,

(2) that it would suffer irreparable injury if the injunction is not granted,

(3) that an injunction would not substantially injure other interested parties, and

(4) that the public interest would be furthered by the injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)).

The four factors should be balanced on a sliding scale, and a party can compensate for a lesser showing on one factor by making a very strong showing on another factor. *CSX Transp., Inc. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005) (citing *CityFed Fin. Corp.*, 58 F.3d at 747).

However, it is particularly important for Teva to demonstrate a substantial likelihood of success on the merits. *Cf. Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam). Absent a "substantial indication" of likely success on the merits, "there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (internal quotation omitted). Because interim injunctive relief is an extraordinary form of judicial relief, courts should grant such relief sparingly. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). As the Supreme Court has said, "[i]t frequently is observed that a preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Id.,* 520 U.S. at 972 (citation omitted).

II. TEVA CANNOT SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS

A. Teva Does Not Have A Cause Of Action To Force The FDA To Delist Pfizer's Patent

The FDA has decided that Pfizer is entitled to pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(B) that delays Teva's final approval. *FDA Decision* at 9-10. The FDA's decision fits reasonably within the statute. The relief Teva seeks – immediate approval of its ANDA – is tantamount to asking this Court to delist Pfizer's '303 patent as of the date of the Federal Circuit's March 22, 2007 decision in favor of ***Apotex***. That relief is not available as a matter of law. The relevant statute, 21 U.S.C. § 355(j)(5)(C)(ii)(I), reads:

> (I) In general.— ***If an owner of the patent or the holder of the approved application*** under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent ***brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim***

> ***either—***
>
> > ***(aa) the drug for which the application was approved; or***
> >
> > ***(bb) an approved method of using the drug.***

Id. (emphasis added).

However, Congress made this counterclaim provision the applicant's exclusive remedy, and did not give any court the jurisdiction to allow frustrated applicants to sue the FDA to compel removal of the listing from the Orange Book:

> (II) ***No independent cause of action.— Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I)***.

21 U.S.C. § 355(j)(5)(C)(ii)(II) (emphasis added). Congress' intent is clear – if an ANDA sponsor wants to delist a patent from the Orange Book, it must get into a patent infringement lawsuit with the patent or NDA holder so that it can get an Article III patent court, which is the only proper forum, to decide the issue. There is no other judicial remedy.

B. Even *If* Teva Had A Right Of Action, The Pediatric Exclusivity Law Does Not Help It

The effect of pediatric exclusivity on a Paragraph IV ANDA depends on the status of the ANDA holder's patent litigation. On the one hand, there is the situation where the generic applicant has prevailed against the patented pediatric exclusivity holder, which is covered in *Apotex's Motion for A Preliminary Injunction* and *Apotex's Memorandum Of Points And Authorities In Support Of Its Motion For Preliminary Injunction To Order The FDA To Immediately Grant Approval To Apotex's Anda For Amlodipine And Require FDA To Order Mylan To Stop Marketing Its Generic Amlodipine And For Other Relief*, filed Apr. 23, 2007 ("4/23 Apotex Mem."). For the reasons discussed therein, Apotex – and only Apotex – is

entitled to final approval at this time because only Apotex has prevailed in patent litigation with Pfizer. On the other hand, in Teva's case, where there is no patent suit at all, its Paragraph IV certification is converted to a Paragraph II certification at the time of patent expiration.[1] Thereafter final approval is delayed by pediatric exclusivity under § 355a(c)(2)(A)(ii). This approach was upheld in *Ranbaxy Laboratories v. FDA*, 307 F. Supp.2d 15 (D.D.C.), *aff'd.*, 96 Fed. App. 1 (D.C. Cir. 2004).

C. The FDA's Reading Of The Statute Overcomes Teva's Reliance On Blonder Tongue

The FDA has required each applicant to obtain its ***own*** victory over the NDA holder or the patent holder to avoid application of the NDA-holder's pediatric exclusivity. This reading follows 21 U.S.C. § 355a(c)(2)(B), which requires that the determination of invalidity or non-infringement happen "in the patent infringement litigation resulting from the certification" and that "the court determines" the result. Thus, the FDA was reasonable in concluding that court judgments involving third parties do not benefit an applicant (like Teva) that was never involved in patent litigation. Therefore, if Teva wants the benefit of collateral estoppel (which it has not even argued the elements of) and the benefits of the Federal Circuit holding in *Blonder Tongue*, it should have gone to district court and sued Pfizer in the first instance for a declaratory judgment of invalidity.

III. THE PUBLIC INTEREST IS SERVED BY DENYING TEVA'S MOTION FOR A PRELIMINARY INJUNCTION

The public interest is best served by denying the requested injunctive relief, as the public's interest lies in the "faithful application of the laws" (*Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998)), which, here, is served by requiring the agency to

[1] The same result applies if patent litigation is unresolved as of the date of the patent expiration.

apply the governing statute in a manner that is consistent with FDA's prior judicially-approved rulings and the controlling statutory language. Injunctive relief would not comport with the purpose of the statute and, in particular, the need to properly interpret the pediatric exclusivity provisions as well as the need to give proper respect to court judgments. Any other result will undermine the balance struck in Hatch-Waxman and the pediatric exclusivity law.

IV. APOTEX WILL BE IRREPARABLY HARMED IF TEVA IS ALLOWED ONTO THE MARKET

A decision to order the FDA to approve Teva's ANDA would seriously harm Apotex. If the preliminary injunction is granted, and Teva sells its generic drug, Apotex stands to lose a significant portion of its opportunity to fight for a leadership position in the marketplace as an early entrant. Having that leadership position is essential to capture a sizable portion of the amlodipine market and associated annual sales that are forecasted to reach the hundreds of millions of dollars – harms for which there is no legal redress. Loss of market share in a highly competitive industry is irreparable harm because of the difficulty of recovering from a loss of market share. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 595-96 (3d Cir. 2002).

Representatives from both parties that are seeking to establish a leadership position in the market for generic amlodipine tablets have offered declarations supporting the proposition that irreparable harm is caused by not obtaining this leadership position, which is otherwise impossible to attain. *See* McIntire Decl. (for Apotex) (attached as Exhibit B to 4/23 Apotex Mem. (Dkt. 47)); Roman Decl. (for Mylan) (attached as Exhibit C to 4/23 Apotex Mem. (Dkt. 47)). The existence of irreparable harm arising from not getting the market share that the party is entitled to is undisputed by the parties. One thing standing between Apotex and the market leadership it deserves in the true generic drug market is the FDA's approval of other undeserving

generics. If Apotex loses any part of the head start that it has earned by being the only generic form to prevail in patent litigation against Pfizer, Apotex cannot replace that position with any remedy at law.

V. THE BALANCE OF THE HARMS BETWEEN APOTEX AND TEVA IS NEUTRAL

Both Apotex and Teva are seeking to enter the same market with the same problems of having a permanent market-share disadvantage with not being on the market. Courts have noticed that claims of irreparable harm to oneself when the other party suffers the identical harm, indicate a balance of the harms. *See Express One Intern., Inc. v. U.S. Postal Serv.*, 814 F. Supp. 87, 91 (D.D.C. 1992) (stating that the court has recognized irreparable injury when a party lost the renewal of a contract to another bidder).

CONCLUSION

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

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Respectfully submitted,

/s/Arthur Y. Tsien

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