IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES, INC., *et al.*, Plaintiffs, and MUTUAL PHARMACEUTICAL CO., INC. Intervenor-Plaintiff, v. MICHAEL O. LEAVITT, Secretary, Health and Human Services, *et al.* Defendants and TEVA PHARMACEUTICALS USA, INC., Intervenor-Defendant, and APOTEX INC., Intervenor-Defendant.	Civil Action No. 07-0579 (RMU)

MUTUAL PHARMACEUTICAL CO., INC.'S MEMORANDUM IN SUPPORT OF MYLAN'S APPLICATION FOR A PRELIMINARY INJUNCTION

Intervenor-Plaintiff Mutual Pharmaceutical Co., Inc. ("Mutual") respectfully submits this Memorandum in Support of Mylan Laboratories Inc.'s and Mylan Pharmaceuticals Inc.'s (collectively "Mylan") Application for a Preliminary Injunction ("Mylan's PI Motion") and in response to the oppositions filed by Apotex Inc. ("Apotex") and the federal defendants ("FDA") on April 26, 2007. Mylan requests a

preliminary injunction to prevent FDA from issuing a final approval of Apotex's amlodipine ANDA if and when the Federal Circuit issues a final mandate in Pfizer, Inc. v. Apotex, Inc., No. 2006-1261 (the "Apotex case") on the invalidity of Pfizer's U.S. Patent No. 4,879,303 ("the '303 patent"). The injunction requested in Mylan's PI Motion is warranted to preserve the status quo until a final decision on the merits can be reached by this Court.

In its April 18, 2007 letter ruling (the "FDA Decision"), FDA made the following determinations:

- the Federal Circuit's March 22, 2007 decision in the Apotex case is not effective to render the '303 patent invalid until the Court's mandate issues;
- as a result, when the '303 patent expired on March 25, 2007, it was a valid patent;
- under long-standing FDA practice, which has been upheld by the D.C. Circuit Court of Appeals, Paragraph IV certifications in unapproved ANDAs converted to Paragraph II certifications at the "magic moment of midnight" on March 25, 2007, when the '303 patent expired; and
- ANDAs containing Paragraph II certifications are blocked from approval by Pfizer's pediatric exclusivity until September 25, 2007 under 21 U.S.C. § 355a(c)(2)(A).

As set forth more fully in Mutual's April 26, 2007 Opposition to the Preliminary Injunction Motions filed by Teva and Apotex, FDA's determinations with respect to these issues is well-supported by the pediatric exclusivity statute, FDA's prior practice and binding precedent. FDA erred, however, with respect to one, narrow issue.

Specifically, without pointing to any statutory provision or expression of Congressional intent, FDA determined that Apotex would be immediately entitled to final approval if and when the Federal Circuit mandate issues. This decision by FDA was arbitrary and capricious, and it should be overturned by this Court.

Mutual therefore requests that this Court enjoin FDA from implementing that part of the FDA Decision that finds Apotex's ANDA eligible for approval upon issuance of the Federal Circuit's final mandate in the Apotex case. Under binding precedent, Apotex was required to convert to a Paragraph II certification when the '303 patent expired, and approval of Apotex's ANDA should be delayed by Pfizer's pediatric exclusivity. If, as FDA seems to suggest, Apotex is allowed to maintain its Paragraph IV certification, then approval of Apotex's ANDA is alternatively delayed by Mylan's 180-day exclusivity period. There is simply no statutory or regulatory mechanism by which Apotex can avoid Mylan's exclusivity period without converting to a Paragraph II certification. Given the urgency of the relief sought in this action, Mutual urges the Court to grant Mylan's PI Motion to enable Mylan and Mutual to be fully heard on their Complaints should the Federal Circuit issue a final mandate in the Apotex case.

I. APOTEX IS SUBJECT TO PFIZER'S PEDIATRIC EXCLUSIVITY

As FDA and Apotex both concede, long-standing FDA practice and binding precedent dictate that, when the '303 patent expired, all pending ANDAs – including Apotex's ANDA – were required to convert to Paragraph II certifications. There can be no dispute that an ANDA with a Paragraph II certification is subject to Pfizer's pediatric exclusivity. The relevant statutes provide no mechanism for converting Apotex's Paragraph II certification back to a Paragraph IV certification, and neither FDA nor

Apotex can point to any such mechanism. As such, Mylan's PI Motion should be granted.

The "critical event" for determining the existence of pediatric exclusivity is "the expiration of the patent." See 21 U.S.C. § 355a; Ranbaxy Labs. v. FDA, 307 F. Supp. 2d 15, 19 (D.D.C. 2004), aff'd, 96 Fed. Appx. 1 (D.C. Cir. 2004). The '303 patent expired at midnight on March 25, 2007. For purposes of determining the applicability of pediatric exclusivity for the '303 patent, FDA must look at the state of affairs as they existed upon patent expiration on March 25.

FDA determined that the Federal Circuit's decision in the Apotex case will not be effective until the Federal Circuit issues its mandate. (FDA Decision at 7.) As a result, when the '303 patent expired, the district court decision finding that the '303 patent was valid and infringed by Apotex still controlled the parties' rights and obligations with respect to the '303 patent.

At the "magic moment" of midnight on March 25, Apotex's ANDA contained a Paragraph IV certification to an expired patent that was found to be valid and infringed by the district court. See Ranbaxy Labs., 307 F. Supp. 2d at 20. At that point, Apotex's Paragraph IV certification either became a Paragraph II certification, or FDA was entitled to treat it as a Paragraph II certification. Id. And as FDA recognizes, ANDAs containing Paragraph II certifications to the '303 patent are blocked from receiving final approval until the expiration of Pfizer's pediatric exclusivity on September 25, 2007. (FDA Decision at 8-9; see also FDA Opposition at 31-32.) This is as true for Apotex as it is for

Teva or any other applicant holding an unapproved amlodipine ANDA with a Paragraph IV certification to the '303 patent when it expired.[1]

In its April 26, 2007 opposition to Mylan's PI Motion, Apotex effectively recognized that its Paragraph IV certification is no longer valid by squarely adopting the position that a Paragraph II certification is the proper certification when a patent expires. In challenging the applicability of Mylan's 180-day exclusivity period after the expiration of the '303 patent, Apotex relies on the Hatch-Waxman provisions relating to Paragraph II certifications, which provide that ANDAs should be approved "immediately" when the ANDA filer submits a Paragraph II certification and asserts that any relevant patents have expired. (Apotex Opposition at 8; citing 21 U.S.C. § 355(j)(5)(B)(i).) Notably, Apotex also discusses at length Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003), and argues that the rationale set forth in that case should be applied by this Court in addressing Mylan's exclusivity period. (Apotex Opposition at 9-10.)

Apotex is correct that the rationale in Dr. Reddy's should be applied here, but Apotex fails to mention the entire holding of Dr. Reddy's. Specifically, the Dr. Reddy's court upheld FDA's determination that a Paragraph IV filer is *required* to convert its Paragraph IV certification to a Paragraph II certification upon patent expiration. Dr. Reddy's, 302 F. Supp. 2d at 354-55. Apotex cannot have it both ways – if it wants to rely on Dr. Reddy's, it is bound by the holding set forth therein.

[1] Apotex contends that its Paragraph IV certification should not be converted to a Paragraph II certification because it had obtained a favorable decision by the Federal Circuit, thus "satisf[ying] the Paragraph IV requirements." (Apotex Opposition at 5-6.) This argument, however, ignores FDA's well-founded determination that the Federal Circuit's decision is not final and binding until the mandate issues. (See, e.g., Mutual's April 26, 2007 Opposition to the Preliminary Injunction Motions filed by Teva and Apotex at 5-9.) Moreover, once the '303 patent expired, there can be no dispute that Apotex's Paragraph IV certification did not accurately reflect the current state of the facts, which could only be accomplished through a Paragraph II certification.

Nevertheless, FDA created an exception for Apotex that finds no support in the statute (or elsewhere) when it decreed that Apotex would no longer be subject to Pfizer's pediatric exclusivity if and when the Federal Circuit issues a mandate invalidating the '303 patent. (FDA Decision at 8-9.) When the '303 patent expired at midnight on March 25 – the critical event for determining the applicability of pediatric exclusivity – Apotex did not have an effective decision of invalidity of the '303 patent. That the Federal Circuit may issue a mandate in the future invalidating the '303 patent is irrelevant. The only date that matters for purposes of determining the applicability of pediatric exclusivity is the day the patent expires, and, at that time, Apotex's Paragraph IV certification converted to a Paragraph II certification, subjecting Apotex's ANDA to Pfizer's pediatric exclusivity until September 25. See 21 U.S.C. § 355a(c)(2)(A). This is the only result that is consistent with the statute, prior FDA practice and the binding caselaw affirming it.[2]

II. APOTEX'S ANDA IS SUBJECT TO MYLAN'S 180-DAY EXCLUSIVITY PERIOD

If Apotex is not required to convert its Paragraph IV certification to a Paragraph II certification, approval of its ANDA is undoubtedly subject to Mylan's 180-day exclusivity period. In prior decisions, FDA and the courts have determined that the 180-day exclusivity period no longer applies after patent expiration only because all pending ANDA filers are required to change their Paragraph IV certifications to

[2] At the same time, such a result is consistent with Congressional intent to elevate the goal of obtaining more drugs that are safe for pediatric use over the goal of accelerating the availability of generic competition to those drugs. See S. Rep. No. 107-79, at 11 (2001) ("By granting drug manufacturers a 6-month extension of market exclusivity for a drug upon satisfactory completion of requested pediatric studies of the product and delaying the availability of lower cost generic alternatives, the bill will make those prescription drugs . . . more expensive . . . . There would also be cost savings . . . by, for example, the reduced need for hospitalization of children and reduced error in medicating children.").

Paragraph II certifications. See, e.g., Ranbaxy Labs., 307 F. Supp. 2d at 19-20; Dr. Reddy's, 302 F. Supp. 2d at 354-55. As such, the 180-day exclusivity set forth in 21 U.S.C. § 355(j)(5)(B)(iv) simply cannot apply. Without the change to a Paragraph II certification, however, there is simply no statutory or regulatory mechanism for Apotex to avoid Mylan's exclusivity period. To the extent that FDA asserts that Mylan somehow forfeited its exclusivity period with respect to ANDA filers maintaining Paragraph IV certifications, the FDA Decision is arbitrary and capricious and unsupportable by the Hatch-Waxman statute and regulations. As such, the Court should grant Mylan's PI Motion until a full determination can be made on the merits relating to Mylan's 180-day exclusivity period.

FDA's and Apotex's assertions that the plain language of the statute and FDA's prior rulings support the proposition that the generic exclusivity holder forfeits its exclusivity period when the relevant patent expires is misplaced. (FDA Decision at 10-11; Apotex Opposition at 8-10.) Notably, FDA and Apotex rely entirely on the Hatch-Waxman provisions relating to Paragraph II certifications and court decisions in which it was determined that a proper certification upon patent expiration is a Paragraph II certification. (FDA Decision at 10-11; Apotex Opposition at 8-10; citing, among other things, 21 U.S.C. § 355(j)(5)(B)(i) and Dr. Reddy's, 302 F. Supp. 2d at 354-55.)[3] The reason for this is clear – a Paragraph II certification is the only statutory and regulatory mechanism to avoid the 180-day exclusivity period when the relevant patent expires. In fact, the courts in the two cases relied upon by Apotex – Dr. Reddy's and Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 126 (D.C. Cir. 2006) – both adopt the position that the

[3] FDA explains this in quite some detail in its April 26, 2007 opposition to Mylan's PI Motion. (FDA Opposition at 40-41.)

exclusivity period is avoided upon patent expiration by the submission of a Paragraph II certification. Of course, as discussed above, Apotex should have made such a certification here and should thus be precluded from receiving final approval by virtue of Pfizer's pediatric exclusivity period. Absent a conversion to a Paragraph II certification, however, there is no statutory or regulatory mechanism by which Apotex can avoid Mylan's 180-day exclusivity period.

Through the Hatch-Waxman Amendments, Congress established an incentive structure to encourage generic applicants to challenge brand patents with the express purpose of enhancing generic market competition. 21 U.S.C. § 355(j)(5)(B)(iv)(I); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 n. 11 (D.C. Cir. 1998) (exclusivity grant an important incentive); see also Understahl, B., Authorized Generics: Careful Balance Undone, 16 Fordham Intell. Prop. Media & Ent. L.J. 355, 365 (2005). The 180-day exclusivity period was the cornerstone of this incentive structure. Mylan Pharm., Inc. v. Shalala, 81 F.Supp.2d 30, 44 (D.D.C. 2000) ("The 180-day exclusivity provision was specifically adopted to reward generic drug makers who . . . undertake the potentially time-consuming and costly efforts to establish that a pioneer drug maker's patent is wrongfully keeping generic drugs off the market."); see also Understahl, B., 16 Fordham Intell. Prop. Media & Ent. L.J. at 365. To the extent that FDA has determined that Mylan has somehow simply forfeited its exclusivity period with respect to all ANDA filers maintaining Paragraph IV certifications, FDA has ignored this Congressionally-established incentive structure without statutory support.

Neither the plain language of the Hatch-Waxman Amendments nor the relevant regulatory provisions authorize forfeiture of the 180-day exclusivity period in the event a

challenged patent expires during the period of exclusivity. See 21 U.S.C. § 355(j)(5)(B)(iv); see also 21 C.F.R. § 314.107. It is therefore impermissible for the FDA to now authorize forfeiture of this earned exclusivity, since the statute is silent on the issue. See, e.g., Ranbaxy Labs., 469 F.3d at 125 (noting pattern of D.C. Circuit decisions "reject[ing] at *Chevron* step one the FDA's attempt to add statutory requirements for exclusivity").

If Congress intended patent expiration to constitute a forfeiture of the exclusivity period, it certainly could have said so. In fact, Congress did just that in the 2003 Medicare Modernization Act ("MMA"). Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2457 (2003) (altering the language of 21 U.S.C. § 355(j)(5)(B)(iv)(I)). Through the MMA, Congress specifically provided that the 180-day exclusivity period would be forfeited by the first Paragraph IV filer when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired." 21 U.S.C. § 355(j)(5)(D)(i)(VI). Clearly, this provision would have been unnecessary if the Hatch-Waxman Amendments already provided that patent expiration would extinguish all exclusivity rights. 1A Singer, N., Sutherland's Statutory Construction § 22.30, at 366 (6th ed. 2002) ("a statutory amendment is presumed to have been intended to change the law"); see also Planned Parenthood Fed'n of America v. Heckler, 712 F.2d 650, 658 n. 39 (D.C. Cir. 1983) ("a change in statutory language may presumptively indicate a change of legislative intent," although legislative history may rebut the presumption).

Notably, unlike other provisions of the MMA, Congress did not make the patent expiration forfeiture provision retroactive. See, e.g., Pub. L. No. 108-173, § 1102(b)(1),

117 Stat. at 2460 (limiting application of the MMA, with exception, to those drug applications filed "after the date of the enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of the enactment of this Act"). Compare Pub. L. No. 108-173, § 1102(b)(2),(3) (identifying collusive agreements retroactive to the effective date of the MMA). Thus, FDA is bound by clear Congressional directives in the Hatch-Waxman Amendments and in the adoption of the MMA. FDA's decision to ignore these directives and not recognize Mylan's rightful exclusivity period is improper.

CONCLUSION

Without the relief requested in Mylan's PI Motion, Mylan and Mutual will not have a fair opportunity to be heard on their respective Complaints. The Court should grant Mylan's application for a preliminary injunction to preserve the status quo by enjoining FDA from approving Apotex's ANDA in the event that the Federal Circuit issues a final mandate.

Dated: April 27, 2007

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of April, 2007, Intervenor-Plaintiff Mutual Pharmaceutical Co., Inc.'s Memorandum in Support of Mylan Laboratories Inc.'s and Mylan Pharmaceuticals Inc.'s Application for a Preliminary Injunction was filed with the Clerk of the Court using the CM/ECF system, which will automatically send e-mail notification of such filing to the attorneys of record listed below. In addition, a true and correct copy was served on the attorneys of record listed below by electronic mail and Federal Express.

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