IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC. and MYLAN PHARMACEUTICALS INC., Plaintiffs, and MUTUAL PHARMACEUTICAL CO., INC., Intervenor-Plaintiff, v. MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, ANDREW C. VON ESCHENBACH, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants, and TEVA PHARMACEUTICALS USA, INC., and APOTEX INC., Intervenor-Defendants.	Civil Action No. 07-CV-579 (RMU)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MYLAN'S MOTION FOR RECONSIDERATION OF THE OPINION AND ORDER DENYING MYLAN'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Reconsideration of an order under the Federal Rules of Civil Procedure is appropriate to correct a clear error or to alleviate a manifest injustice. *See Cobell v. Norton*, 224 F.R.D. 266, 271 (D.D.C. 2004) (discussing reconsideration under Rule 59(e)); *cf. id.* at 271–72 (discussing reconsideration under Rule 54(b)). In its opinion denying Mylan's motion for a preliminary injunction, this Court relied on the pediatric exclusivity provisions of the Best Pharmaceuticals for Children Act (BPCA)[1] pertaining to paragraph IV certifications, despite the fact that the FDA converted Apotex's ANDA to a paragraph II certification upon patent expiration. Op.[2] at 15–16.

Mylan respectfully submits that Apotex's ANDA must be treated as a paragraph II certification for all purposes. As a matter of fact, the FDA converted Apotex's paragraph IV certification to a paragraph II certification when the '303 patent expired on March 25. The mistaken assumption that Apotex retained its paragraph IV certification led the Court to apply § 355a(c)(2)**(B)** of the BPCA, which governs paragraph IV certifications. The Court should have applied § 355a(c)(2)**(A),** which governs paragraph II applications and unambiguously provides that such applications *shall not* be approved for six months after patent expiration. Once the facts are properly understood and the correct statutory provision applied, it is evident that Mylan is highly likely to prevail on the merits of its challenge to the FDA's threatened approval of Apotex's ANDA. This high probability of success lessens the severity of the harm Mylan must demonstrate to warrant issuance of a preliminary injunction.

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[1] Pub. L. No. 107-109, 115 Stat. 1408 (2002).

[2] *Memorandum Opinion* [Dkt. No. 67] (hereinafter "Op.").

ARGUMENT

THE COURT SHOULD RECONSIDER ITS DECISION IN LIGHT OF ITS MISAPPREHENSION OF THE STATUS OF APOTEX'S ANDA ONCE THE '303 PATENT EXPIRED

A. THE FDA CONVERTED APOTEX'S PARAGRAPH IV CERTIFICATION TO A PARAGRAPH II CERTIFICATION

As this Court correctly noted, when a patent expires before a paragraph IV ANDA receives final approval, the FDA's long-standing practice is to treat all paragraph IV applicants as having converted their certifications to paragraph II certifications. Op. at 15. The Court found, however, that "although [the FDA] had previously deemed all paragraph IV certifications as paragraph II certifications when Pfizer's patent expired," the FDA concluded that "this result in this case would be contrary to the congressional intent of Hatch-Waxman." Op. at 15. But the FDA's April 18 decision shows that this is *not* what happened in this case:

> . . . FDA determines as follows. When the '303 patent expired on March 25, 2007, all of the unapproved ANDAs were required to change (or deemed to have changed) to paragraph II certifications and became subject to Pfizer's pediatric exclusivity at that time. That is their status during the period before the mandate issues.

Ltr.[3] at 9.[4] It is undisputed that at the time the '303 patent expired, Apotex had an "unapproved ANDA[]." Apotex's paragraph IV certification therefore was "deemed to have changed" to a paragraph II certification upon the patent's expiration.

What the FDA really held in the April 18 decision was that *even though* Apotex's ANDA converted to a paragraph II certification, the FDA will not block approval of the application on

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[3] Letter from Gary J. Buehler dated April 18, 2007 [Dkt. No. 40-2].

[4] *See also Government Defendants' Combined Memorandum in Opposition to Motions for Injunctive Relief Filed by Teva, Apotex, and Mylan* [Dkt. No. 52] (hereinafter "FDA Opp.") at 32 ("Thus, FDA concluded that, when the '303 patent expired on March 25, 2007, all of the certifications to that patent contained in the unapproved ANDAs were required to change (or deemed to have changed) to paragraph II certifications . . . .").

the basis of pediatric exclusivity once the mandate issues. That is, the FDA recognized an "exception to the application of the Hatch-Waxman certification provisions," not an exception to the FDA's long-standing practice of converting IVs to IIs upon patent expiration. Ltr. at 9.

The Court considered Apotex a paragraph II filer when addressing Mylan's claim for 180-day exclusivity. The Court explained that "when Pfizer's Norvasc patent expired on March 25, 2007, all paragraph IV certifications converted to paragraph II certifications and became eligible for approval." Op. at 19. The FDA's April 18 decision and its opposition to Mylan's preliminary injunction motion confirm that the FDA converted Apotex's paragraph IV certification to a paragraph II certification. Apotex's ANDA must therefore be treated as a paragraph II application for purposes of pediatric exclusivity.

B. THE FDA HAS NO LEGAL BASIS TO EXEMPT APOTEX FROM PARAGRAPH II PEDIATRIC EXCLUSIVITY

In its motion for a preliminary injunction, Mylan argued that under the BPCA, the FDA cannot lawfully approve Apotex's paragraph II ANDA during the period of pediatric exclusivity. The Court rejected Mylan's argument on the basis of § 355a(c)(2)**(B)**, which applies only to paragraph IV applications. The Court should have applied 21 U.S.C. § 355a(c)(2)**(A)**, which governs paragraph II ANDAs and plainly states that "if the drug is the subject of a listed patent for which certification has been submitted under [paragraph II] . . . and for which pediatric studies were submitted prior to the expiration of the patent . . . the period during which [a paragraph II] application may not be approved . . . *shall* be extended by a period of six months" (emphasis added). Where a statute is clear on its face, the inquiry into its meaning ends because Congress's intent is unmistakable. "When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is

clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842–43 (1984). And "when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." *Lamie v. United States Trustee*, 540 U.S. 526, 534 (2004) (quotations and citations omitted); *see also Ratzlaf v. United States*, 510 U.S. 135, 147–48 (1994) ("[W]e do not resort to legislative history to cloud a statutory text that is clear.").

In light of the FDA's patent disregard of the applicable subsection, § 355a(c)(2)(**A**), Mylan has demonstrated a high likelihood of succeeding on the merits of its challenge to the FDA's newly-created "Apotex exception."

C. MYLAN IS ENTITLED TO A PRELIMINARY INJUNCTION DUE TO THE FDA'S IMMINENT APPROVAL OF APOTEX'S PARAGRAPH II ANDA

This Court recognized in its opinion that the factors relevant to injunctive relief "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." Op. at 10. "'An injunction may be justified . . . where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury.'" *Id.*, quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995). The Court denied Mylan's motion for a preliminary injunction "[p]rimarily" because Mylan "fail[ed] to show a substantial likelihood of success on the merits and irreparable injury." Op. at 22. As demonstrated above, when one takes proper account of the FDA's treatment of Apotex's ANDA, it becomes evident that Mylan has an exceptionally high likelihood of succeeding on the merits. And given this likelihood, the balance of the relevant factors weighs in favor of a preliminary injunction. When a government agency expresses its intention to violate a clear statutory mandate, a movant should not be

required to show that its very existence is in jeopardy in order to receive a preliminary injunction against the irreparable harms it stands to suffer.[5]

CONCLUSION

For the foregoing reasons, Mylan asks this Court to reconsider its opinion and order denying Mylan's motion for a preliminary injunction, and to grant the preliminary injunction in Mylan's favor.

[5] The Court's ruling conflicts with precedents holding that loss of market exclusivity *does* constitute irreparable harm. *See Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997) (finding irreparable harm where the FDA deprived a party of its "180-day statutory grant of exclusivity"); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (granting preliminary injunction and acknowledging that "there is a significant economic advantage to receiving first approval and being the first company to enter the market, *an advantage that can never be fully recouped through money damages or by 'playing catch-up*'") (emphasis added).

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Respectfully submitted,

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