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)

MYLAN'S REPLY IN SUPPORT OF ITS MOTION FOR RECONSIDERATION

The FDA's three-page opposition, a single paragraph of which is devoted to Mylan's motion for reconsideration, does not address the issue raised by Mylan's motion: the fact that this Court considered the legality of the FDA's threatened approval of Apotex's ANDA under § 355a(c)(2)**(B)**, which governs paragraph IV applications, rather than § 355a(c)(2)**(A)**, which governs paragraph II applications. Indeed, the FDA does not even acknowledge that the Court applied the wrong statutory provision. It is well and good for the FDA to say that this Court "squarely considered this issue and the arguments made by Mylan," Gov. Opp.[1] at 3 (citing "slip op. at 15-16"), but a reading of pages 15 and 16 of the Memorandum Opinion[2] only reinforces the conclusion that the Court upheld the FDA's "interpretation" of the wrong statute.

In its opposition the FDA does *not* dispute that:

- ". . . Apotex's paragraph IV certification [was] converted to a paragraph II certification . . ." Gov. Opp. at 2.
- Section 355a(c)(2)**(A)** governs the application of pediatric exclusivity to paragraph II certifications. Ltr.[3] at 8.
- This Court mistakenly found that the FDA had "depart[ed] from its long-standing practice" in this case and therefore did *not* convert Apotex's ANDA to a paragraph II certification. Mem. Op. at 16.
- Based on the mistaken belief that Apotex had retained its paragraph IV certification, the Court reviewed the legality of the FDA's "Apotex exception" under § 355a(c)(2)**(B)**, which governs the

[1] *Government Defendants' Opposition to Motions for Reconsideration Filed by Apotex and Mylan* [Dkt. No. 71].

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

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

applicability of pediatric exclusivity to paragraph IV applications. Mem. Op. at 14.[4]

In order to properly rule on Mylan's challenge to the FDA's threatened approval of Apotex's ANDA, the Court must consider that approval in light of the applicable statutory provision, § 355a(c)(2)**(A)**, which provides that "if the drug is the subject of a listed patent for which a 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). The FDA has never explained how it can interpret § 355a(c)(2)**(A)**, which unequivocally instructs that the period during which paragraph II ANDAs may not be approved "shall be extended" for six months following patent expiration, to permit an exception for an ANDA filer that "affirmatively wins its patent litigation." Gov. Opp. at 2. It simply has repeated the mantra that "the facts of this case presented unusual circumstances that warranted finding this exception in order to effectuate Congressional intent." Gov. Opp. at 2-3.[5]

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[4] At the same time, the Court treated Apotex's ANDA as having been converted to a paragraph II certification when it ruled that Mylan's 180-day generic exclusivity under § 355(j)(5)(B)(iv) ended upon patent expiration. Mem. Op. at 18-19 ("[Section 355(j)(5)(B)(iv)] by its terms, applies only to paragraph IV certification, which cease to exist upon patent expiration.").

[5] *See also* Ltr. at 8-9 ("This is the first time that FDA has been called upon to determine whether an ANDA applicant is subject to the innovator's pediatric exclusivity when the ANDA applicant has received a *favorable* court decision in its paragraph IV litigation but has not yet obtained final approval when the patent expires. . . . FDA believes that the language of the statute manifests a clear Congressional intent that pediatric exclusivity not block the approval of an ANDA where the ANDA applicant has

(Footnote continued)

But *Chevron* and its progeny do not permit an agency to so easily avoid the plain meaning of an Act of Congress. *Chevron* instructs that "[i]f 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); *see also Lamie v. United States Trustee*, 540 U.S. 526, 534 (2004) ("It is well established that 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.") (quotations and quotation marks omitted). The D.C. Circuit Court of Appeals has recognized this principle time and time again, emphasizing that agencies may not create exceptions to clear statutory mandates. *See, e.g., Sierra Club v. EPA*, 129 F.3d 137, 138 (D.C. Cir. 1997) ("The [Clean Air Act] does not provide for any grace periods or other exemptions from the conformity requirements for areas designated as nonattainment areas, nor does it authorize the EPA to create such exemptions."); *id.* at 140 ("[T]his court has consistently struck down administrative narrowing of clear statutory mandates."); *New York v. EPA*, 413 F.3d 3, 41 (D.C. Cir. 2005) (*per curiam*) ("Absent clear congressional delegation . . . EPA lacks authority to create an exemption from [New Source Review] by administrative rule."); *Southern California Edison Co. v. FERC*, 195 F.3d 17, 24 (D.C. Cir. 1999) ("Under *Chevron* an agency may not 'avoid the Congressional intent clearly expressed in the text simply by

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prevailed in the paragraph IV patent litigation and therefore creates an exception to the application of the Hatch-Waxman certification provisions.") (emphasis in original).

asserting that its preferred approach would be better policy.'"), quoting *Engine Mfr. Ass'n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996). In this case, the FDA's effort to effectuate its notion of Congressional intent by creating an exception for Apotex is wholly unauthorized; Congress left no gap for the FDA to fill. *See Railway Labor Executives' Ass'n v. Nat'l Mediation Board*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*).

When an order reflects a clear error or would result in a manifest injustice, reconsideration of the order is appropriate. See *Cobell v. Norton*, 224 F.R.D. 266, 271 (D.D.C. 2004) (discussing reconsideration under Rule 59(e)); *cf. id.* at 272 (noting that reconsideration under Rule 54(b) is proper where a court has misapprehended the facts). Mylan does not seek to "reargue the grounds it argued previously," Gov. Opp. at 2, it seeks a ruling, on the merits, based on consideration of the proper statute. That, due to the Court's misapprehension concerning the status of Apotex's ANDA upon patent expiration, has yet to occur in this case.

Dated: May 9, 2007

Respectfully submitted,

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