UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

GOVERNMENT DEFENDANTS' OPPOSITION TO MOTIONS FOR RECONSIDERATION FILED BY APOTEX AND MYLAN

Plaintiff Mylan and intervenor Apotex have moved for reconsideration of this Court's Memorandum Opinion and Order entered on April 30, 2007. Both of these motions are without merit and should be denied.

The grounds for Apotex's motion arise from the patent litigation regarding the '303 patent that Apotex lost to Pfizer in January 2006 in United States District Court in Illinois. That patent litigation is discussed by the Court in its Memorandum Opinion. *See Mylan Labs., Inc. v. Leavitt*, Civ. No. 07-0579 (RMU), 2007 U.S. Dist. LEXIS 31170, slip op. at 8, 13-16 (D.D.C. April 30, 2007). Apotex claims that it was successful in having the district court injunction

entered by the Illinois court lifted by order of March 29, 2007. Because of this order lifting the injunction, Apotex claims that its ANDA should be approved immediately, and Apotex submitted a request for such approval to FDA on May 1, 2007. (Apotex's May 1 letter to FDA is Attachment C to its motion for reconsideration). As explained in the attached letter from FDA to Apotex dated May 7, 2007, FDA denied Apotex's request for immediate approval of its ANDA, concluding that the "lifting" of the injunction does not change FDA's conclusion that the approval of Apotex's ANDA is not appropriate at this time. Among other things, FDA noted: "The March 29 Order is not a final effective decision that the patent is invalid or not infringed." FDA letter at 3. FDA also noted that it was first made aware of this March 29 order on April 27, when it was attached to Apotex's reply brief submitted to this Court. The reasoning in FDA's letter is consistent with the reasoning in its letter decision of April 18, 2007, and with this Court's Memorandum Opinion at 15-16. As this Court recognized, slip op. at 16, this is clearly a situation in which "FDA's decision reasonably resolves the ambiguity in applying the relevant statutes to a factual situation not fully foreseen or provided for by the Congress when it enacted the statutes. . . ." *Mylan Labs., Inc. v. Thompson,* 389 F.3d 1272, 1284 (D.C. Cir. 2004). Rather than re-state the reasoning provided in FDA's May 7 letter, that letter is attached hereto and incorporated into this opposition.

Mylan, in its motion for reconsideration, merely seeks to reargue the grounds it argued previously. Mylan asserts that once Apotex's paragraph IV certification converted to a paragraph II certification, pediatric exclusivity attached, and that is the end of the matter. Mylan asserts that it is impermissible for FDA to find an exception to that process when the ANDA applicant affirmatively wins its patent litigation. Mylan Reconsideration Brief at 2-3. FDA found, however, that the facts of this case presented unusual circumstances that warranted finding this

exception in order to effectuate Congressional intent. FDA Decision at 9. Moreover, this Court squarely considered this issue and the arguments made by Mylan, and upheld FDA's decision. *See Mylan Labs.,* slip op. at 15-16. Mylan's brief adds nothing new that requires reconsideration. *See Judicial Watch, Inc. v. Dep't of Energy,* 319 F. Supp.2d 32, 34 (D.D.C. 2004) ("The purpose of a motion for reconsideration is not to repeat arguments which the Court has already found unpersuasive."), *aff'd in part, rev'd in part on other grounds,* 412 F.3d 125 (D.C. Cir. 2005); *New York v. United States,* 880 F. Supp. 37, 38 (D.D.C. 1995) (A "motion to reconsider is not simply an opportunity to reargue facts and theories upon which a court has already ruled.").

For the foregoing reasons, the motions for reconsideration should be denied.

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/s/

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