IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS INC., and MATRIX LABORATORIES LTD., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant, and RANBAXY LABORATORIES LTD., Intervenor-Defendant.	Case No. 1:11-cv-00566-JEB

PLAINTIFFS' SURREPLY MEMORANDUM IN OPPOSITION TO DEFENDANT FOOD AND DRUG ADMINISTRATION'S MOTION TO DISMISS

Pursuant to LCvR 7, Plaintiffs Mylan Pharmaceuticals Inc. ("Mylan") and Matrix Laboratories Limited ("Matrix") (collectively "Plaintiffs"), by and through their attorneys, respectfully submit this Surreply Memorandum in Opposition to the Motion to Dismiss filed by Defendant Food and Drug Administration ("FDA"). This Surreply addresses a recent decision, *ViroPharma, Inc. v. Hamburg*, C.A. No. 10-1529-ESH (D.D.C. April 15, 2011) ("*ViroPharma* Mem. Op."), "chiefly relied" upon by FDA in its

Reply Memorandum in Support of Motion to Dismiss ("Reply Memorandum").[1] *See* FDA's Reply Memorandum at ii, iii; LCvR 7(a).

As demonstrated below, FDA's reliance on *ViroPharma* for its argument that Plaintiffs lack standing is misplaced because the circumstances underlying *ViroPharma* are very different from those presented here. In *ViroPharma*, the court held that the plaintiff, ViroPharma, did not have standing to sue because its claim of injury was based solely on the possible occurrence of numerous highly speculative events and only if FDA made a particular decision. Here, Plaintiffs have demonstrated that FDA's failure to act is causing them immediate, concrete injury (as well as harm to the public at large) unless FDA makes a decision soon one way or the other.

Moreover, FDA's contention that the speculative nature of potential ANDA approvals in *ViroPharma* is similar to the probability of Matrix's atorvastatin ANDA approval is flawed. Indeed, the circumstances underlying the two cases could not be more different -- whereas ViroPharma could supply the court with no information about the status of its competitors' ANDAs (and approval of at least one of those ANDAs was critical to ViroPharma's case), Plaintiffs here have provided the Court with extensive information establishing that FDA approval of Matrix's atorvastatin ANDA is close at hand.

---

[1] *ViroPharma* was issued the same day that FDA filed its Reply Memorandum and four days after Plaintiffs filed their Consolidated Reply Memorandum in Support of their Motion for a Preliminary Injunction and Opposition to Defendants' Motion to Dismiss.

I. *ViroPharma* Presented Very Different Circumstances Than Are Present Here.

Unlike Plaintiffs, which are generic drug manufacturers attempting to foster generic competition for one of the most widely prescribed branded drugs, ViroPharma, a brand drug manufacturer seeking to protect its profits, sought to deter generic competition. Fearing that FDA would approve ANDAs for the generic version of its branded Vancocin by permitting generic ANDA sponsors to rely only on *in vitro* (i.e., laboratory) as opposed to *in vivo* (i.e., human) testing to demonstrate bioequivalence, ViroPharma filed a lawsuit against FDA. The crux of ViroPharma's complaint was that a prior FDA decision on a citizen petition for a different drug (acarbose) amended a FDA regulation without notice and comment rulemaking, thereby permitting ANDA sponsors to rely on *in vitro* testing for demonstrating bioequivalence when seeking FDA approval of their ANDAs. ViroPharma's suit was *not* based on any specific determination or decision by FDA concerning bioequivalence methods for generic versions of ViroPharma's branded Vancocin product, and was not based on any alleged failure of FDA to make a decision or otherwise act (as Plaintiffs have alleged in the present case). Instead, ViroPharma's suit was based on a prior, unrelated FDA decision. *ViroPharma* Mem. Op. at 3-4.

II. The Chain of Speculative Events in *ViroPharma* Relied Upon to Establish Injury Is Dramatically Different from the Cause of Plaintiffs' Injury.

ViroPharma's claim of injury was based on the possible occurrence of four different, speculative events: 1) *if* ANDAs submitted by its potential competitors relied

on *in vitro* testing; 2) *if* FDA's prior acarbose decision applied to generic versions of Vancocin; 3) *if* FDA permitted *in vitro* testing for generic Vancocin ANDAs; and 4) *if* FDA approved ANDAs for generic Vancocin. The court found that, based on ViroPharma's chain of "ifs" and speculations about possible future events, ViroPharma had not demonstrated that it was "substantially probable" that FDA's prior decision would result in injury to ViroPharma or that ViroPharma was suffering, or would in all likelihood suffer, from harm "fairly traceable" to FDA's prior acarbose decision. *Id.* at 6-8, 10.

Tellingly, the court did not deny ViroPharma standing *solely* because FDA had not yet approved a generic Vancocin ANDA, as FDA portrays. *See* FDA Reply Mem. at 4. Instead, the court tied its denial of standing to ViroPharma's inability to demonstrate any link between the unrelated acarbose prior decision and ViroPharma's alleged future injuries. *ViroPharma* Mem. Op. at 11.

The chain of speculative "ifs" that caused the court to deny ViroPharma standing simply does not exist in this case. To the contrary, and as demonstrated in Plaintiffs' prior filings, it is "substantially probable" that FDA's failure to make a decision – one way or the other – whether Ranbaxy's atorvastatin ANDA has marketing exclusivity has caused, and is causing, significant financial and other concrete harms to Plaintiffs, and that such harms are "fairly traceable" to FDA's arbitrary, capricious and unlawful failure to make that decision.[2]

[2] *See* Plaintiffs' Consolidated Reply Memorandum in Support of Plaintiffs' Motion for a Preliminary Injunction and Memorandum in Opposition to Defendants' Motions to

III. Speculation Surrounding FDA Approval of ANDAs in *ViroPharma* Is Diametrically Different from the High Likelihood of Approval of Matrix's ANDA.

FDA also attempts to equate the uncertainty surrounding FDA approval of ViroPharma's potential competitors' ANDAs with the prospects for approval of Matrix's *own* atorvastatin ANDA. Because the *ViroPharma* court decided that FDA approval of generic Vancocin ANDAs was too speculative, FDA argues that this Court must likewise decide that Mylan and Matrix lack standing. FDA Reply Mem. at 4. However, unlike ViroPharma, which had no access to information about the status of FDA's review of ANDAs submitted by its potential competitors, Plaintiffs have significant information about the review status of Matrix's atorvastatin ANDA, and with that information, have demonstrated to this Court that FDA approval is forthcoming and not speculative. *See* Plaintiffs' Memorandum in Support of Motion for a Preliminary Injunction at 9, 26; Plaintiffs' Consolidated Reply Memorandum at 4-12.[3] Because Matrix's atorvastatin ANDA likely will be approved in the imminent future, Plaintiffs have demonstrated that it is more than "substantially probable" that FDA's inaction is causing them real, quantifiable, harm, unlike the purported harm alleged in *ViroPharma.* *See* Mauro Declaration ¶¶ 8, 17-20; Babu Declaration ¶¶ 5-27.

Dismiss (filed April 11, 2011) (Docket No. 26) at 32-37; Declaration of Dr. Hari Babu (filed under seal March 24, 2011 (Docket No. 6, Att. No. 3) ¶¶ 7-11, 14-27; Declaration of Anthony Mauro (filed under seal March 24, 2011 (Docket No. 6, Att. No. 14) ¶¶ 8-22, 17-20.

[3] For example, Plaintiffs have not been informed by FDA of "any open deficiencies with the Matrix ANDA," and, to the best of Plaintiffs' knowledge, there are no open deficiencies with the Matrix ANDA. Declaration of S. Wayne Talton ¶ 11 (Dk. No. 6); Talton Supplemental Declaration ¶¶ 7-10, 18 (Dk. No. 24) (both filed under seal).

IV. Conclusion

For these reasons, and the reasons previously stated by Plaintiffs, this Court should find that Plaintiffs have standing to seek their requested relief.

Dated: April 22, 2011

Respectfully submitted,

MYLAN PHARMACEUTICALS INC. and
MATRIX LABORATORIES LTD.

By: /s/ Karla L. Palmer

Douglas B. Farquhar (D.C. Bar No. 386573)
Karla L. Palmer (D.C. Bar No. 444353)
Kurt R. Karst (D.C. Bar No. 482615)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329

Attorneys for Plaintiffs