UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RANBAXY LABORATORIES, LTD. and RANBAXY, INC., Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of Health and Human Services; MARGARET HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs; and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	No. 1:14-cv-1923-BAH

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR EXPEDITED RULING ON PENDING MOTIONS

In light of recent developments, and as described in further detail below, Plaintiffs Ranbaxy Laboratories, Ltd. and Ranbaxy, Inc. (collectively, "Ranbaxy") renew their request for preliminary injunctive relief and respectfully move this Court to take prompt action on the pending motions for preliminary injunctive relief (Docket # 41) and summary judgment (Docket # 51, #53).

Earlier this afternoon, Defendants Sylvia Mathews Burwell, Margaret Hamburg, M.D., and United States Food and Drug Administration (collectively, "FDA") filed a notice in this Court formally announcing (1) FDA's determination that Ranbaxy has forfeited its right to 180-day marketing exclusivity for generic Nexium® products, and (2) FDA's approval of an ANDA for generic Nexium® filed by Ivax Pharmaceuticals, Inc. ("Ivax"). *See* Notice, Dkt. No. 67 at 1-

2. As the Court is well aware, Ranbaxy's lawsuit maintains that Ranbaxy has a legal right to 180-day marketing exclusivity for both generic Valcyte® and generic Nexium® products and that FDA therefore is barred as a matter of law from approving any other company's ANDA for either of those products while the Company's exclusivity rights remain in force. With today's action, FDA has again done precisely what Ranbaxy filed its pending motion to prevent.

This development underscores the need for a prompt decision in this case. FDA's notice concedes that its action removes any jurisdictional impediment to this Court's resolution of Ranbaxy's claims regarding either of the products at issue in this litigation. Dkt. No. 67 at 2. And FDA's approval of yet another competing ANDA product—this time for generic Nexium®—renders prompt action essential. As Ranbaxy has explained, the loss of its exclusivity rights threatens to impose literally hundreds of millions of dollars in damages for which Ranbaxy has no remedy at law. *See Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010). Alongside the already-mounting damages from FDA's approval of competing ANDAs for generic Valcyte®, FDA's decision to allow a competing generic Nexium® applicant to launch its product will magnify the losses Ranbaxy is and has been incurring since this litigation commenced in early November.

This Court previously recognized the need for a prompt resolution of this litigation, when it expedited the briefing schedule for the pending motions and consolidated Ranbaxy's motion for preliminary injunctive relief with a hearing on the merits. Minute Order, 11/21/14 (citing a need "to conserve the resources of the parties and the Court while expeditiously resolving the proposed motions of the parties"). For the same reasons, and particularly in light of today's developments, Ranbaxy renews its request for preliminary injunctive relief and respectfully requests that this Court promptly issue its disposition in this matter—either granting Ranbaxy the

relief it has requested (which would stem the mounting damages Ranbaxy is incurring from FDA's unlawful action) or denying that relief promptly (so that Ranbaxy can continue pursuing its claims on appeal). In either case, time is of the essence.

CONCLUSION

For the foregoing reasons, Ranbaxy renews its pending motion for preliminary injunctive relief and respectfully requests that this Court promptly issue its rulings on the pending motions.

Dated: January 26, 2015

Respectfully submitted,

By:/s/ Michael D. Shumsky
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CERTIFICATE OF SERVICE

The undersigned certifies that on this 26th day of January, 2015, he caused the foregoing MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR EXPEDITED RULING ON PENDING MOTIONS to be served upon the following via the Court's CM/ECF system:

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