IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS, INC., *et al.*	)	
Plaintiff,	)	
v.	)	Civil Action No. 1:11-cv-00566-JEB
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
Defendant.	)	

INTERVENOR-DEFENDANT RANBAXY LABORATORIES LIMITED'S ("RANBAXY") REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS THE COMPLAINT

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INTRODUCTION

Put simply, the lawsuit brought by Mylan Pharmaceuticals, Inc. and Matrix Laboratories, Ltd. (collectively "plaintiffs") seeks to force the defendant U.S. Food and Drug Administration ("FDA") to truncate its ongoing evaluation of the intervenor-defendant Ranbaxy's ANDA, to strip Ranbaxy of its hard-earned statutory right to 180-day exclusivity for generic Lipitor®, and to deny the ANDA FDA's normal review process. Compl. 4, 22-23.[1] Plaintiffs brush aside the fact that there has been no final agency action to render this case ripe for judicial review by asserting presumptuously and cavalierly that "FDA has all of the information it needs to make a decision" (Pls. Opp'n Br. 18) and that therefore the Agency's failure to do *right now* what plaintiffs would like it to do constitutes unreasonable agency delay. Plaintiffs, however, do not come close to showing, as they must to state a claim for unreasonable delay, that the Agency's deliberation on this issue has been "egregious." *Cobell v. Norton*, 240 F.3d 1081, 1096 (D.C. Cir. 2001) (internal quotation, citation omitted). Indeed, the procedures FDA is following in this matter are no different from the procedures it routinely follows when considering questions of ANDA applications and exclusivity, and plaintiffs are situated no differently from any other generic drug companies that have applied to FDA for approval of an ANDA and are waiting for the Agency to make an exclusivity determination.

Where plaintiffs particularly fall short, among other places addressed by FDA in its moving papers and reply, is in their casual disregard for the importance of the 180-day marketing exclusivity incentive to the overall scheme and goals of the Hatch-Waxman Act ("Hatch-

[1] Plaintiffs try to understate the scope of the relief requested in their papers opposing Ranbaxy's and FDA's motions to dismiss (Pls.' Opp'n Br. 13), but the complaint could not be clearer. Compl. 23, Prayers for Relief (c) (seeking a declaration that "there is no applicable period of 180-day marketing exclusivity for generic Lipitor® at issue . . . .) and (e) seeking that FDA be "[e]njoin[ed] . . . from withholding final approval of Matrix's atorvastatin ANDA on the basis that Ranbaxy's 180-day marketing exclusivity blocks Matrix's atorvastatin ANDA from receiving approval . . .); *id.* at 4, ¶¶ 8-9 (alleging that the AIP "should be enforced against the Ranbaxy ANDA" and that "if [the] FDA enforces the AIP against the Ranbaxy ANDA, then the plain language of the FDC Act and the AIP require FDA to deny Ranbaxy's ANDA").

Waxman"), and their failure to appreciate the reluctance of the courts to undermine this incentive. In plaintiffs' world, getting their generic product on the market as soon as possible takes precedence over a considered, careful decision by FDA on whether Ranbaxy is entitled to marketing exclusivity because of its challenges to the Pfizer patents for Lipitor®. But in the Hatch-Waxman world that Congress envisioned and created and that the courts have recognized, the 180-day exclusivity creates the main incentive for generic companies to challenge questionable brand company patents and to pave the way for generic competition, and is deserving of broad protection. Plaintiffs' efforts to force FDA into a rushed denial of Ranbaxy's exclusivity, and to deprive Ranbaxy of the process its ANDA is due under Hatch-Waxman and the AIP, would severely undermine the 180-day incentive and, therefore, the very same Hatch-Waxman interests that plaintiffs purport to be championing. Plaintiffs' efforts would also act to deprive Ranbaxy of due process protections to which Hatch-Waxman and FDA regulations entitle it should FDA determine that its ANDA must be denied. In short, given the interests on the other side of the equation from plaintiffs', FDA's actions with respect to Ranbaxy's ANDA and its right to exclusivity cannot possibly be deemed unreasonable, much less egregious. For these reasons, and for the reasons set forth in Ranbaxy's opening brief, plaintiffs' Complaint should be dismissed.

ARGUMENT

I. Plaintiffs' Efforts to Strip Ranbaxy of Exclusivity Directly Contravene the Purposes of Hatch-Waxman.

There is no dispute that a principal goal of the Hatch-Waxman Act is to "expedite the marketing of generic drugs." *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008). *See also In re Barr Lab., Inc*., 930 F.2d 72, 76 (D.C. Cir. 1991) (Hatch-Waxman intended by Congress to "get generic drugs into the hands of patients at reasonable prices – fast."). It is equally clear, however, that Congress determined that the goal of accelerated generic competition would be best served by affording generic companies a financial incentive to challenge brand company patents through the so-called paragraph IV certification process, and that in enacting Hatch-Waxman, it chose 180-day exclusivity as the means to that end. 21 U.S.C. § 355(j)(5)(B)(iv). *See also Teva Pharm., USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) ("Th[e] promise of initial marketing exclusivity is . . . intended to increase [generic] competition by expediting the availability of generic equivalents."); *Teva v. Leavitt*, 548 F.3d at 104 (noting that Hatch-Waxman generic exclusivity "is valuable," and that its purpose is "to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders.") (citations omitted); *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) ("As an incentive for generic pharmaceutical companies to undertake the risk of litigation and further the statutory purpose of accelerating public access to lower-cost drugs, the first ANDA-applicant that files a paragraph IV certification is entitled to a 180-day period of generic marketing exclusivity.") (citation omitted).

By definition, a grant of exclusivity delays full generic competition, and under the pre-2003 version of Hatch-Waxman that is indisputably applicable to this case, a recipient of exclusivity is able to delay triggering its exclusivity and thereby to delay generic competition

altogether.[2] As noted in FDA's opening brief, however, courts have been extremely reluctant to undermine the exclusivity incentive, recognizing that it is Congress' chosen vehicle for advancing the pro-consumer goals of Hatch-Waxman, even when the exclusivity incentive somehow limited or compromised generic competition in the short term.

For example, last year, in *Teva v. Sebelius*, *supra,* Teva, the generic company claiming exclusivity as the "first-filer" of an ANDA containing a paragraph IV certification for a generic version of the brand product Cozaar®, challenged FDA's interpretation of a Hatch-Waxman provision (as amended by the MMA), that would have deprived it of 180-day exclusivity. The effect of denying Teva exclusivity would have been to allow other generic companies with ANDAs for generic Cozaar® to enter the market immediately, and FDA argued that depriving Teva of exclusivity would advance the Hatch-Waxman goal of accelerated generic competition. The D.C. Circuit's response, however, made clear that undermining the exclusivity award is not consistent with, and cannot be claimed to be an advancement of, the pro-consumer goals of Hatch-Waxman.

> [T]he FDA's sole effort to root its interpretation in the policy underlying Hatch-Waxman – the thought that the interpretation benefits consumers by allowing full generic competition without a 180-day delay – betrays a misunderstanding of the exclusivity incentive. The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device

[2] The version of Hatch-Waxman applicable to this case is the version that predated amendments to Hatch-Waxman contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003). This pre-2003 version allowed for the "parking" of generic exclusivity, such that an award of exclusivity could effectively preclude generic competition even after the award was made, until the recipient was ready to exercise the right. Thus, until Congress amended the statute in 2003 to create certain conditions of forfeiture of exclusivity in the event it was not exercised in a timely manner, Congress recognized that preserving the incentive was more important than immediate generic competition. While plaintiffs suggest that somehow the 2003 changes to Hatch-Waxman should retroactively inform the way this Court views the exclusivity right claimed by Ranbaxy, and the way Congress weighed the statute's goals in the pre-2003 version (Pls.' Opp'n Br. 21 n. 14), the fact of the matter is that there is no case of which we are aware in which a court denied an award of exclusivity to advance the goal of generic competition, before or after 2003.

> Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.

595 F.3d at 1318. *See also Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) (applying the pre-MMA version of Hatch-Waxman to preserve a first-filer's entitlement to the exclusivity incentive in the face of an FDA interpretation of the statute that would have denied the applicant exclusivity and noting that "[t]he FDA may not . . . change the incentive structure adopted by Congress").

Likewise here, plaintiffs' efforts to force FDA into a quick denial of Ranbaxy's exclusivity, far from promoting Hatch-Waxman's pro-consumer goals, eviscerates Congress' chosen means of advancing these goals. Put another way, given the repeatedly acknowledged importance of the exclusivity incentive in the Hatch-Waxman scheme, it is completely reasonable for FDA to act with care and deliberation before determining whether stripping Ranbaxy of its statutory right to such exclusivity is warranted. Ranbaxy engaged in precisely the activity that the incentive structure under Hatch-Waxman was designed to promote. It invested time and money to design around the brand patents, it undertook the risk of costly patent litigation, it obtained a ruling from the United States Court of Appeals for the Federal Circuit determining that the only asserted claim of one of Pfizer's patents was invalid, and generic atorvastatin products will be brought to market sooner because of its hard-earned success. As a

result, Ranbaxy has earned the incentive that Congress promised, and that incentive cannot be taken away rashly, as plaintiffs would require.

Plaintiffs' efforts to analogize this case to *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26 (D.D.C. 2006), is futile. In that case, a plaintiff drug company successfully challenged FDA's delay on its *own application*. *Id.* at 31 ("The plaintiff challenges the defendant's inaction in processing the plaintiff's application for a new drug application for the drug Omnitrope."). FDA's failure to act on that application did not implicate a statutory right enjoyed by another company, and the relief requested did not "change the incentive structure adopted by the Congress." *Ranbaxy*, 469 F.3d at 126. In other words, the kinds of competing considerations that exist in this case, and that counsel against the rash approach plaintiffs urge, were simply not present. Given the importance of generic exclusivity to the Hatch-Waxman structure, and the effect of the relief requested by plaintiffs, if awarded, on Ranbaxy's rights, it is eminently reasonable for FDA to have declined plaintiff's demands to act in haste, and application of the *TRAC* factors compel dismissal of the complaint in this case.

II. Plaintiffs' Request for Immediate Relief Would Deprive Ranbaxy of the Due Process Rights Accorded to it Under Hatch-Waxman.

Plaintiffs' lawsuit should be dismissed for the additional reason that plaintiffs' request that FDA deny Ranbaxy's ANDA would strip Ranbaxy of the due process protections afforded ANDA applicants under Hatch-Waxman and FDA regulations in cases where the Agency determines that an ANDA cannot be approved. As discussed above, the stakes are even higher in this case, because Ranbaxy is a first filer and is entitled to 180 days of marketing exclusivity. Ranbaxy cannot begin to avail itself of that exclusivity until it has obtained approval of its ANDA. But even if exclusivity were not at issue, by asking the Court to deny the ANDA, Compl. 4, ¶¶ 8-9, plaintiffs are not only trying to wrest control from FDA by truncating the

Agency's review process, but they also are effectively asking the Court to deny Ranbaxy the due process rights to which it is entitled and the process that has been set forth via statute and/or regulation to properly handle these determinations. Plaintiffs have no right to do so.

Hatch-Waxman and FDA's regulations set forth the circumstances under which FDA may deny an ANDA. *See* 21 U.S.C. § 355(j)(4) ("Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds . . . ."); *see also* 21 C.F.R. § 314.127. If FDA decides to deny an application it will issue a "complete response letter" to the applicant informing it that its application has been denied. 21 C.F.R. § 314.110. An applicant may then request an opportunity for a hearing on FDA's decision denying its application. 21 U.S.C. § 355(j)(5)(C) ("If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable.").

In turn, FDA has 60 days from the date of the request for a hearing to either approve the ANDA or refuse to approve the ANDA, in which case the applicant is given written notice of an opportunity for a hearing "on the question of whether there are grounds for denying approval of the . . . [ANDA] under section 505. . . (j)(4) of the act. . . ." 21 C.F.R. § 314.110(b)(3). If, after a hearing before FDA, the Agency persists in its determination that the ANDA should be denied, the applicant can seek judicial review of FDA's decision. *See* 21 U.S.C. § 355(h) ("An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of the application under this section.").

These extensive due process rights are afforded to any ANDA applicant in order to ensure that an application is not wrongly denied by the Agency. The importance of these due process safeguards is even more pronounced in this case, where Ranbaxy is not just an ANDA

holder, but also is the first filer and entitled to exclusivity. Through the injunctive relief requested in this case, plaintiffs seek to nullify the procedural protections to which Ranbaxy is entitled. Where, as here, there has been no final action by FDA on Ranbaxy's ANDA, and plaintiffs erroneously complain that the Agency has engaged in "unreasonable delay," the Court should consider, in reaching its decision on Ranbaxy's Motion to Dismiss, that the relief sought by plaintiffs will not only undermine the exclusivity incentive and deny Ranbaxy its rights to that incentive, but will also deprive Ranbaxy of due process.

III. This Matter Could Well Be Resolved Without Recourse to Judicial Intervention

Given the important interests at stake on Ranbaxy's side of the equation, FDA's delay in addressing Ranbaxy's ANDA and the exclusivity issue is in no way unreasonable or egregious. This is especially true because, as a practical matter, there are many ways in which these issues could be resolved without the need for judicial intervention. Plaintiffs' call for an injunction that would force FDA into truncating Ranbaxy's due process rights and into undercutting the key Hatch-Waxman incentive for generic competition may well be unnecessary, and is certainly premature.

For example, as FDA has pointed out, if Matrix's ANDA is not approved or tentatively approved, there is no basis for plaintiffs to complain about FDA's treatment of Ranbaxy's ANDA and its entitlement to exclusivity. Plaintiffs' assertion in their opposition papers that in fact, "the Matrix ANDA is approvable in the near future" (Pls.' Opp. Br. 4) is nothing more than speculation, and in plaintiffs' complaint, the uncertain fate of the Matrix ANDA is made clear. Compl. at 14, ¶ 49 (stating that plaintiffs "*could* obtain approval of [their] product as early as June 28, 2011, upon completion of FDA's regulatory review process") (emphasis added).

Moreover, as FDA also notes in its opening brief (FDA Br. 11), the Agency and Ranbaxy are engaged in ongoing and confidential discussions to resolve the issues raised in FDA's

February 25, 2009 to Ranbaxy. These discussions, too, may change the alignment of parties interested in these issues.

Finally, the Hatch-Waxman Act itself provides a procedural mechanism by which Ranbaxy's exclusivity could be triggered, and plaintiffs' concerns about undue delay put to rest without judicial intrusion into FDA's province. The statute provides that subsequent ANDA filers – like the plaintiffs themselves – can seek a declaratory judgment of invalidity/non-infringement/unenforceability of the relevant brand company patent. Such a declaratory judgment, if granted in this case, would act to trigger Ranbaxy's 180-day exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002). *See also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064-65 (D.C. Cir. 1998). (In cases involving the post-MMA version of Hatch-Waxman, such a court decision would potentially effect a forfeiture of exclusivity (21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).) Indeed, plaintiff Mylan attempted to trigger Ranbaxy's exclusivity by seeking a declaratory judgment against the Pfizer Lipitor® patents, but ultimately abandoned this effort and chose instead to settle with Pfizer. There are, however, as plaintiffs acknowledge, other later-filers for generic Lipitor® besides plaintiffs. It is certainly possible that one of these applicants will follow the course that has been abandoned by plaintiffs in favor of this ill-advised litigation, and will seek to trigger Ranbaxy's exclusivity through a declaratory judgment action against Pfizer. In short, much could still happen on the matters at issue here to resolve or moot plaintiffs' claims, and plaintiffs' request for judicial intervention is premature.

CONCLUSION

For the foregoing reasons, and for the reasons stated in Ranbaxy's Memorandum in Support of its Motion to Dismiss the Complaint, Ranbaxy's Motion to Dismiss should be granted.

Dated: April 15, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 15th day of April, 2011, she caused a copy of Intervenor-Defendant Ranbaxy Laboratories Limited's Reply Memorandum in Support of Motion to Dismiss the Complaint to be served via the Court's CM/ECF system on the following parties:

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