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 LIMITED,

Intervenor-Defendant.

Civil Action No. 11-566 (JEB)

MEMORANDUM OPINION

The Food and Drug Administration is currently reviewing the application of Ranbaxy Laboratories to have temporary exclusive rights to market a generic drug. Matrix Laboratories, a competitor that has a subsequent application pending for the same drug, eagerly wishes to know the result of Ranbaxy's application. In fact, Matrix and its distributor Mylan Pharmaceuticals have now brought this injunctive action to force the FDA to act on Ranbaxy's application. Because the interrelated concepts of standing and ripeness preclude such expansive subject matter jurisdiction, the Court declines the invitation.

I. Factual and Procedural Background

A. The ANDA Process

Mylan Pharmaceuticals, Inc. and Matrix Laboratories, Ltd. are the would-be distributor and manufacturer of generic atorvastatin, a cholesterol-lowering medicine commonly known by its brand name, LIPITOR®. Compl. at ¶¶ 2, 4. Pfizer, Inc. has sold LIPITOR® without competition from generic versions for 15 years. Id. at ¶¶ 2, 34. The pediatric exclusivity period associated with certain LIPITOR® patents expires, however, on June 28, 2011, at which time drug manufacturers who are able to obtain the Food and Drug Administration's approval for their generic versions of LIPITOR® may begin to market and distribute their products. Id. at ¶ 4 n.1.

FDA approval is required before any drug can be marketed in the United States. See Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). In order to obtain approval for a "pioneer" or "innovator" drug, a drug manufacturer must submit a new drug application ("NDA") to the FDA in accordance with the requirements of § 355(b). An NDA necessarily contains the results of extensive scientific testing performed on the drug to ensure that it is safe and effective. Id. Once approved, patents for the pioneer drug are listed in Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book," available at http://www.fda.gov/cder/ob/. See § 355(b)(1). Since Congress enacted the Hatch-Waxman Amendments to the FDCA in 1984, manufacturers of generic versions of approved drug products may seek FDA approval by filing an abbreviated new drug application ("ANDA"). See § 355(j)[1]; Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998). An ANDA applicant must show that its generic drug is the bioequivalent of the

[1] The parties agree that, because the Ranbaxy ANDA was submitted to the FDA prior to December 8, 2003, the Medicare Modernization Act of 2003's amendments to § 355(j) do not govern the present action. See Compl. at ¶ 41; FDA Mot. at 6 n.6. All references in this Opinion to § 355(j) are thus references to the 2002 version of that statute.

pioneer drug and has the same active ingredient, strength, dosage form, route of administration, labeling, and conditions of use. § 355(j).

An ANDA must also include, for each Orange Book patent implicated by the generic drug, one of four certifications indicating whether the proposed generic drug would infringe that patent and, if not, why not. § 355(j)(2)(A)(vii); Mova, 140 F.3d at 1063. If an ANDA applicant seeks to market its generic drug prior to the expiration of the patents for the brand name drug, it must make a "paragraph IV" certification. Such certification states that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." § 355(j)(2)(A)(vii)(IV). Once a generic drug manufacturer files an ANDA with a paragraph IV certification, however, the ANDA applicant has by law infringed the underlying patent and may be sued by the patent-holder for infringement. See 35 U.S.C. § 271(e)(2)(A).

As an incentive to encourage generic drug manufacturers to challenge existing drug patents – often a lengthy and expensive process – and bring generic drugs to the market, the Hatch-Waxman Amendments offer the first generic drug manufacturer to file an ANDA containing a paragraph IV certification (and ultimately obtain FDA approval for its drug) a 180-day period of marketing exclusivity free from competition from other generic drug manufacturers. See 21 U.S.C. § 355(j)(5)(B)(iv). Numerous cases in this Circuit involving disputes over the 180-day exclusivity period indicate it is a coveted advantage and the cause of heated competition among generic drug manufacturers to secure their status as "first." See, e.g., Hi-Tech Pharmacal Co., Inc. v. FDA, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) (collecting cases).

The FDA may also grant meritorious ANDA applicants tentative approval, even though the applicants may not have been the first to file and even though a competitor may have exclusivity rights. See FDA Mot. at 7 ("FDA grants 'tentative approval' to an ANDA when all

scientific and procedural conditions for approval have been met, but the application cannot be fully approved because approval is blocked by a 30-month stay, some form of marketing exclusivity, or some other barrier to approval arising from patent infringement litigation.") (citing 21 C.F.R. § 314.105(d)).

B. Matrix and Ranbaxy

Plaintiff Matrix submitted its own atorvastatin ANDA more than two years ago, and Plaintiffs recently settled their patent infringement litigation with Pfizer. Id. at ¶¶ 4, 34. [redacted] Plaintiffs allege that Matrix's ANDA should be eligible for approval as early as June 28, 2011, when the pediatric exclusivity period associated with certain LIPITOR® patents expires. Id. at ¶¶ 4 n.1, 35. Matrix's ANDA, however, has not yet received FDA approval, either tentative or final. Id. at ¶ 53 ("FDA has failed to, and continues to refuse to, provide Plaintiffs with any indication or other information concerning whether Matrix's ANDA will be approvable as early as June 28, 2011, or if such approval will be delayed as a result of 180-day marketing exclusivity.").

Although the FDA keeps the status of a pending ANDA confidential, Plaintiffs allege that another generic drug manufacturer, Intervenor-Defendant Ranbaxy Laboratories Ltd., was the first generic drug company to file an ANDA containing a paragraph IV certification and to challenge Pfizer's LIPITOR® patents. Id. at ¶¶ 6-7, 40. Plaintiffs allege that this Ranbaxy ANDA has been pending before the FDA for nearly nine years. Id. at ¶ 7 n.2. Plaintiffs further allege that, under the terms of a settlement agreement with Pfizer, Ranbaxy's ANDA is eligible for approval no earlier than November 2011. Id. at ¶ 7. Accordingly, Plaintiffs allege, if Ranbaxy's ANDA is approved in November 2011 and Ranbaxy is eligible for a 180-day period of marketing exclusivity, then the market for atorvastatin will not be open to other generic

competitors (such as themselves) until at least May 2012. Id. The FDA has not, however, granted Ranbaxy's ANDA tentative approval and has also not announced whether Ranbaxy is entitled to the exclusivity period. Id. at ¶¶ 7 n.2, 10.

Plaintiffs also allege that Ranbaxy's ANDA is subject to a notice issued by the FDA to Ranbaxy invoking the FDA's Application Integrity Policy ("AIP"). Id. at ¶¶ 6, 42-46. Specifically, Plaintiffs allege that on February 25, 2009, the FDA sent Ranbaxy "a letter setting forth numerous allegations with respect to stability test results and other data generated from Ranbaxy's Paonta Sahib [manufacturing] site [in India], including but not limited to data relevant to several pending ANDAs." Id. at ¶ 42. Plaintiffs allege that, pursuant to the FDCA, "if [an] ANDA does not contain reliable data and information, then FDA is expressly prohibited by statute from approving the ANDA." Id. at ¶ 32. This is the statutory mandate, Plaintiffs allege, under which the FDA promulgated its AIP. Id. at ¶ 33; see also 56 Fed. Reg. 46,191 (Sept. 10, 1991). As Plaintiffs interpret the AIP, "Ranbaxy cannot 'cure' any deficiencies with an amendment to that ANDA," but rather must submit a new ANDA and forfeit its position as first-filer (and thus its right to a period of market exclusivity). Id. at ¶ 46. The FDA has not revealed whether Ranbaxy's atorvastatin ANDA is effected by the AIP and has not publicly decided whether, if subject to the AIP, Ranbaxy's ANDA will lose its exclusivity eligibility. Id. at ¶¶ 47-48.

C. The Current Action

Plaintiffs filed their Complaint in this case on March 18, 2011. They assert two claims against the FDA under the Administrative Procedure Act. In Count I, Plaintiffs allege that the "FDA's failure to make a public decision or other determination concerning whether the Ranbaxy ANDA contains unreliable data or information, or otherwise state whether FDA will

enforce the AIP against the Ranbaxy ANDA, rendering the Ranbaxy ANDA ineligible for 180-day marketing exclusivity, is 'agency action unlawfully withheld or unreasonably delayed,' in violation of 5 U.S.C. §§ 706 and 701(b)(2)." Id. at ¶ 68. As relief, Plaintiffs request:

> 1. an injunction requiring FDA to issue an immediate public decision concerning whether the Ranbaxy ANDA is eligible for 180-day exclusivity, so that other generic drug manufacturers can prepare for launch of generic LIPITOR® products; and
>
> 2. a Declaratory Judgment that FDA's failure to make a public decision or other determination concerning whether the Ranbaxy ANDA contains unreliable data or information, or otherwise state whether FDA will enforce the AIP against the Ranbaxy ANDA, rendering the Ranbaxy ANDA ineligible for 180-day marketing exclusivity, is agency action unlawfully withheld or unreasonably delayed.

Id. at ¶¶ 71-72.

In Count II, Plaintiffs allege that the "FDA's failure to approve the Matrix ANDA on the basis of an exclusivity period for the Ranbaxy ANDA is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,' in violation of 5 U.S.C. § 706, because FDA may not approve an ANDA if it contains inaccurate or false data. See 21 U.S.C. § 355(j)(4)." Id. at ¶ 74. As relief, Plaintiffs request:

> 1. an injunction barring FDA from withholding or delaying 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;
>
> 2. a Declaratory Judgment that a grant by FDA of a 180-day marketing exclusivity period to Ranbaxy on its atorvastatin ANDA would be arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of 5 U.S.C. § 706, because FDA may not approve an ANDA if it contains unreliable, inaccurate or false data. See 21 U.S.C. § 355(j)(4); and
>
> 3. a declaratory judgment that FDA must enforce the AIP and immediately deny Ranbaxy's atorvastatin ANDA if any part of the Ranbaxy ANDA is tainted by Ranbaxy's misconduct as set forth in FDA's February 2009 Letter. Such a denial equates to an FDA

> determination that any applicable 180-day marketing exclusivity period for generic LIPITOR® is extinguished.

Id. at ¶¶ 77-79.

On March 24, 2011, Plaintiffs moved the Court for a preliminary injunction ordering the "FDA to promptly issue a decision whether the AIP applies to the Ranbaxy ANDA, and, if so, whether Ranbaxy maintains entitlement to a 180-day exclusivity period that will further delay final approval of ANDAs submitted by Plaintiffs and other generic drug manufacturers." Mot. for P.I. at 4. On March 25, Ranbaxy filed a successful motion to intervene as a defendant. The FDA and Ranbaxy have now filed Motions to Dismiss under Federal Rules of Civil Procedure 12(b)(1), for lack of subject matter jurisdiction, and 12(b)(6), for failure to state a claim. In a telephone conference with chambers, all parties agreed that the Court would consider all pending motions together. See FED. R. CIV. P. 65(a)(2). Given the pendency of a motion for preliminary injunction, the Court required expedited briefing, heard argument on the motions four days ago, and is issuing this Opinion on a similarly accelerated timetable.[2]

II. Legal Standard

In evaluating Defendants' Motions to Dismiss, the Court must "treat the complaint's factual allegations as true . . . and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" Sparrow v. United Air Lines, Inc., 216 F.3d 1111, 1113 (D.C. Cir. 2000) (quoting Schuler v. United States, 617 F.2d 605, 608 (D.C. Cir. 1979)) (internal

[2] In deciding the pending Motions, the Court has reviewed Plaintiffs' Complaint, Plaintiffs' Motion for a Preliminary Injunction, the FDA's Opposition to a Preliminary Injunction and Motion to Dismiss, Ranbaxy's Motion to Dismiss, Plaintiffs' Reply in Support of a Preliminary Injunction and Opposition to the Motions to Dismiss, the FDA's Reply in Support of its Motion to Dismiss, Ranbaxy's Reply in Support of its Motion to Dismiss, and Plaintiffs' Surreply in Opposition to the FDA's Motion to Dismiss. In addition, the Court held a hearing on April 28, 2011.

citation omitted); see also Jerome Stevens Pharms., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005). This standard governs the Court's considerations of Defendants' Motions under both Rules 12(b)(1) and 12(b)(6). See Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) ("in passing on a motion to dismiss, whether on the ground of lack of jurisdiction over the subject matter or for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader"); Walker v. Jones, 733 F.2d 923, 925-26 (D.C. Cir. 1984) (same). The Court need not accept as true, however, "a legal conclusion couched as a factual allegation," nor an inference unsupported by the facts set forth in the Complaint. Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 193 (D.C. Cir. 2006) (quoting Papasan v. Allain, 478 U.S. 265, 286 (1986) (internal quotation marks omitted).

To survive a motion to dismiss under Rule 12(b)(1), Plaintiffs bear the burden of proving that the Court has subject matter jurisdiction to hear their claims. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992); U.S. Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000). A court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority." Grand Lodge of Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). For this reason, "'the [p]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Id. at 13-14 (quoting 5A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1987) (alteration in original)). Additionally, unlike with a motion to dismiss under Rule 12(b)(6), the Court "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." Jerome Stevens, 402 F.3d at 1253; see also Venetian Casino Resort, L.L.C. v. E.E.O.C., 409 F.3d 359, 366 (D.C. Cir. 2005) ("given the present posture of this case – a

dismissal under Rule 12(b)(1) on ripeness grounds – the court may consider materials outside the pleadings").

III. Analysis

The FDA moves to dismiss Plaintiffs' Complaint on the grounds that Plaintiffs lack standing, their claims are not ripe for adjudication, the FDA's enforcement discretion is not reviewable, and Plaintiffs have failed to state a claim for unreasonable delay under the APA. The Court need only reach the first two.

A. Standing

Article III of the United States Constitution limits the jurisdiction of the federal courts to resolving "Cases" and "Controversies." U.S. CONST. art. III, § 2, cl. 1. A party's standing "is an essential and unchanging part of the case-or-controversy requirement of Article III." Lujan, 504 U.S. at 560. To have standing, a party must, at a constitutional minimum, meet the following criteria. First, the plaintiff "must have suffered an 'injury in fact' – an invasion of a legally-protected interest which is (a) concrete and particularized . . . and (b) 'actual or imminent, not "conjectural" or "hypothetical[.]"'" Id. at 560 (citations omitted). Second, "there must be a causal connection between the injury and the conduct complained of – the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" Id. (alterations in original) (citation omitted). Third, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" Id. at 561 (citation omitted). A "deficiency on any one of the three prongs suffices to defeat standing." U.S. Ecology, 231 F.3d at 24.

The FDA argues that Plaintiffs lack standing because they have not, and cannot, allege imminent injury: "Because Mylan's ANDA is not yet ready to be approved, it faces no imminent

injury from the prospect that a competitor might obtain 180-day exclusivity." FDA Mot. at 15. Indeed, "Mylan's ANDA . . . has not received even tentative approval from FDA, indicating that there remain issues concerning whether the application is scientifically approvable," and it is not "by any means certain that Mylan's ANDA will be tentatively approved by June 28, 2011." Id. As a result, "Mylan cannot be injured by any other ANDA holder's exclusivity period if it cannot obtain approval to market its own product for other reasons." Id. at 16.

Plaintiffs maintain that the FDA's failure to notify them whether their potential June 28, 2011, launch will be delayed by a Ranbaxy exclusivity period is causing them irreparable harm. Compl. at ¶¶ 48-49. More specifically, should Plaintiffs prepare to launch generic LIPITOR® on June 28, only to learn that they will be prevented from doing so by a Ranbaxy exclusivity period, they will have wasted significant resources producing medication that will expire before it can be sold. Id. at ¶ 52. Conversely, if Plaintiffs delay in preparing to launch generic LIPITOR®, they risk losing valuable market share by being unable to supply, on short notice, the demand for their drug if Ranbaxy does not obtain exclusivity. Id. at ¶ 51. Such an argument, however, is entirely dependent on the state of Matrix's own ANDA and whether it can be approved by June 28. It is here that Plaintiffs' argument founders.

1. No Tentative Approval

As Plaintiffs concede, they still have not received even tentative approval for their ANDA – a key factor in standing analysis. While acknowledging that "the lack of a tentative approval has occasionally been viewed as a factor in determining whether a plaintiff has standing," Plaintiffs argue that "in numerous decisions, tentative approval is not a predicate for an ANDA sponsor to have standing to challenge FDA (in)action on exclusivity or issues concerning a competitor's ANDA approval." Plfs. Opp. at 6. In support of this position, Plaintiffs rely on four cases from this Circuit: Pfizer Inc. v. Shalala, 182 F.3d 975 (D.C. Cir.

1999); Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191 (D.D.C. 2002); Teva Pharms. USA, Inc. v. FDA, No. 99-67, 1999 WL 1042743 (D.D.C. Aug. 19, 1999);[3] and TorPharm, Inc. v. Thompson, 260 F. Supp. 2d 69 (D.D.C. 2003).

Yet in all of these cases, the plaintiff's standing can be distinguished on one of two grounds. Either the case, unlike here, involved FDA action relating to a plaintiff's own pending ANDA, see Pfizer, 182 F.3d 975 (allowing generic manufacturer Mylan to intervene in suit in which brand-name manufacturer Pfizer challenged the FDA's acceptance of Mylan's ANDA for processing); Purepac, 238 F. Supp. 2d 191 (allowing Purepac to seek review of FDA decision to deny its ANDA); TorPharm, 260 F. Supp. 2d 69 (allowing TorPharm to appeal decision denying it exclusivity), or the plaintiff, unlike here, was a first filer seeking to protect the period of marketing exclusivity it expected to receive upon approval. See Teva v. FDA, 1999 WL 1042743. In none of these four cases did the government even raise a standing challenge. This is because these distinctions carry legal significance.

The legally protected interest in the first category of cases is straightforward: an ANDA applicant has a legally protected interest in the FDA's consideration of its own ANDA, and it might suffer harm as a result of the FDA's denial or neglect. In this case, unlike Pfizer, Purepac, and TorPharm, Plaintiffs do not directly challenge FDA action or inaction with respect to their own ANDA. Neither would Plaintiffs' requested relief – FDA action on Ranbaxy's ANDA – directly affect the status of Plaintiffs' pending ANDA.

The legally protected interest in the second category of cases arises from the statutory grant of a period of marketing exclusivity to the first generic manufacturer to file an ANDA for a

[3] To avoid confusion, this case will be cited as Teva v. FDA, while Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010), will be cited as Teva v. Sebelius.

particular drug – the first filer. See 21 U.S.C. § 355(j)(5)(B)(iv). Just as manufacturers of approved drugs possess an interest in preventing unlawful competition in their markets, see Mova, 140 F.3d at 1074 ("numerous cases have found that a firm has constitutional standing to challenge a competitor's entry into its market"), a generic drug manufacturer, by being first to file, similarly acquires a legally protected interest in the 180-day exclusivity period to which it is statutorily entitled if and when the FDA approves its paragraph IV ANDA. See, e.g., Teva v. Sebelius, 595 F.3d at 1311 ("This 'first-mover advantage' is a valuable asset."). This interest can be the basis for a generic drug manufacturer's standing in a suit over entitlement to exclusivity. See id. at 1312 ("the impending prospect of allegedly unlawful competition in the relevant market" is "the same harm that has sufficed for Article-III injury purposes in all of our past drug-approval cases") (citing Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1497 (D.C. Cir. 1996) ("[W]here . . . a statutory provision reflects a legislative purpose to protect a competitive interest, the protected competitor has standing to require compliance with that provision.")).

Granting first filers pre-tentative-approval standing to challenge the FDA's approval of a competitor's ANDA is at times necessary to prevent imminent harm. Without this standing, first filers who become enmeshed in protracted legal battles with brand-name patent-holders – the very market-opening behavior § 355(j)(5)(B)(iv) was designed to encourage – would have no means of protecting their hard-earned statutory interest in a period of marketing exclusivity. It bears repeating here that the 180-day exclusivity period belongs to the paragraph IV ANDA applicant who files first and then obtains approval, rather than the first paragraph IV ANDA applicant to simply obtain approval. Id.; see also Teva v. Sebelius, 595 F.3d at 1311. It is for this reason that "courts in this circuit routinely reach the merits of generic manufacturers' claims

to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." Id.

Plaintiffs cite the above-quoted language from Teva v. Sebelius as a "key point," see Hearing Tr. at 32:24-33:10, in support of their claim to standing. Yet the Court must view the D.C. Circuit's comments in Teva v. Sebelius in the factual and procedural context of that case. Critical to that court's analysis was the fact that "there [was] no material ambiguity about essential facts." 595 F.3d at 1311. Teva was both the first filer and had already been granted tentative approval. It is against this factual background that the court found that Teva had standing to bring its exclusivity claim. Teva v. Sebelius thus stands for the narrower proposition that where there is no material ambiguity about essential facts – as evidenced in that case by Teva's tentative approval and clear first-filer status – a court may "reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." Id.

Plaintiffs in the present case were not the first to file for approval of a generic version of LIPITOR®, and Matrix's ANDA has not received even tentative approval from the FDA. Plaintiffs have not identified, and conceded at the hearing that they are not aware of, see Hearing Tr. at 17:12-17, any case in which a court in this Circuit has found a subsequent ANDA filer without tentative approval to have standing to compel the FDA to take or not take action with respect to a competitor's pending ANDA. This Court does not believe such an expansion of standing is warranted here.

2. Rights of Third Party

Plaintiffs' task of establishing standing is "'substantially more difficult'" because they allege the FDA unlawfully delayed acting on Ranbaxy's ANDA rather than on their own. Chamber of Commerce v. EPA, No. 09-1237, slip op. at 13 (D.D.C. Apr. 29, 2011) (quoting

Lujan, 504 U.S. at 562) (finding no standing in case filed on behalf of car dealers who sought to challenge emission standards for car manufacturers). It may be possible, under Article III, to establish standing in such a case, id.; as a matter of prudential standing, however, courts have adopted a "general prohibition on a litigant's raising another person's legal rights." Elk Grove Unified Sch. Dist. v. Newdow, 542 U.S. 1, 12 (2004) (quoting Allen v. Wright, 468 U.S. 737, 751 (1984) (internal quotation omitted)); see also Wyoming Outdoor Council v. U.S. Forest Service, 165 F.3d 43, 48 (D.C. Cir. 1999) ("Litigants seeking to assert the rights of third parties . . . have been found to lack standing on prudential grounds."); Pfizer, 182 F.3d at 979 ("the legal rights that will be affected are not Pfizer's but those of its competitors, about which Pfizer is not in a position to complain").

Here, Ranbaxy correctly protests that a judicial decision that acts to abort its FDA review process would violate Ranbaxy's own due process rights. See Ranbaxy's Reply at 6. At the hearing, Ranbaxy articulated its hope that the FDA would act on its ANDA expeditiously, but expressly indicated that it has joined this suit as a defendant, not a plaintiff, because, at least in part, it did not desire to force agency action. Hearing Tr. at 29:18-30:22.

Plaintiffs mistakenly assert that "[r]equiring a plaintiff to have a tentative approval in order to seek relief such as that requested under the circumstances here would mean that FDA could never be held accountable for its delay in rendering a decision." Plfs. Opp. at 6-7. This argument misses the important point that standing depends not only on the existence of a legally protected interest, but also on whose interest it is. Plaintiffs cite § 355(j)(5)(A) as the basis for their claim that the FDA has unreasonably delayed making a decision on Ranbaxy's ANDA. Plfs. Opp. at 16. Yet § 355(j)(5)(A) states: "Within one hundred and eighty days of the initial receipt of an application . . . or within such additional period as may be agreed upon by the

Secretary and the applicant, the Secretary shall approve or disapprove the application." (Emphasis added). The right to a timely ANDA review thus belongs to the ANDA applicant – in this case, Ranbaxy. Plaintiffs may fervently wish for the FDA to act on Ranbaxy's ANDA; such desires, however, do not equate with standing.

3. Effect on Business Decisions

Nor can Plaintiffs successfully allege the injury necessary to obtain standing based on their allegations that the FDA's delay in deciding whether Ranbaxy is entitled to a period of marketing exclusivity "directly affects business decisions that must be made now." Compl. at ¶ 55. Just last month, another court in this Circuit held that standing is not conferred by agency action that creates uncertainties detrimental to a would-be plaintiff's strategic business planning abilities. See ViroPharma, Inc. v. Hamburg, No. 10-1529, 2011 WL 1438400, at *5 (D.D.C., Apr. 15, 2011) (Huvelle, J.). In ViroPharma, the plaintiff alleged, among other injuries, "harms to ViroPharma's ongoing business operations." Id. Specifically, "plaintiff claims that the FDA's regulatory change generally 'impacts ViroPharma's operations, investment decisions, and strategic planning'" and that "ViroPharma's 'ability to construct strategic plans' has been 'impacted' by FDA's actions 'as a result of cash flow uncertainties' . . . and that the 'uncertainty' associated with FDA's actions has caused ViroPharma's stock price to be lower tha[n] it otherwise would be." Id. (internal citations omitted). The Court concluded:

> ViroPharma's allegations present a number of problems, each of which would be sufficient to undercut its rationale for standing. ViroPharma complains that its operations have been variously changed or 'impacted,' . . . and that it suffers from 'uncertainties' regarding the future regulatory and competitive environment. These 'harms' are highly nebulous in both character and degree, and are a far cry from the type of 'concrete and particularized' injury required for Article III standing.

Id.

This Court believes that Judge Huvelle's reasoning is persuasive here, too. Not only are Plaintiffs' alleged harms speculative, but they are so generalized as to be applicable to almost any competitive business situation. To grant standing because of this broad type of potential injury would grossly distort the concept. Cf. Pfizer, 182 F.3d at 979 ("Pfizer voluntarily incurred the expense of preemptive patent litigation in order to get a substantial statutory benefit, namely, a stay of the FDA's approval of Mylan's ANDA. In sum, Pfizer suffers no hardship because it 'is not required to engage in, or to refrain from, any conduct.'") (quoting Texas v. United States, 523 U.S. 296, 301 (1998)).

4. Lack of Redress

Finally, Plaintiffs have not pled facts sufficient to suggest that their injuries are likely to be redressed by the relief they seek. Even were this Court able to force the FDA to 1) enforce the AIP against Ranbaxy – a dubious proposal at best, see Heckler v. Chaney, 470 U.S. 821, 832 (1985) ("an agency's decision not to take enforcement action should be presumed immune from judicial review") – 2) immediately deny Ranbaxy's ANDA, and 3) extinguish Ranbaxy's 180-day marketing exclusivity period, Plaintiffs, whose own ANDA has yet to receive even tentative approval, would still have no more certainty as to whether they may begin to market generic LIPITOR® on June 28, 2011.

The Court, therefore, finds that Plaintiffs lack standing to maintain the present action, thereby warranting dismissal under Rule 12(b)(1).

B. Ripeness

A second related ground also requires granting the FDA's Motion to Dismiss – namely, the doctrine of ripeness. See Wyoming Outdoor Council, 165 F.3d at 48 ("Closely akin to the standing requirement, and indeed not always clearly separable from it, is the ripeness doctrine."). In order to determine whether a controversy is ripe, a court must "evaluate both the fitness of the

issues for judicial decision and the hardship to the parties of withholding court consideration." Pfizer, 182 F.3d at 978 (quoting Texas, 523 U.S. at 301 (internal quotation omitted)).

1. Fitness

A claim "'is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.'" Id. (quoting Texas, 523 U.S. at 300). In other words, the "'fitness' prong of the analysis generally addresses 'whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final.'" Teva v. Sebelius, 595 F.3d at 1308 (quoting National Ass'n of Home Builders v. U.S. Army Corps of Engineers, 440 F.3d 459, 463 (D.C. Cir. 2006)).

a. Factual Uncertainty

The FDA argues first that "Mylan's claims are not fit for review for the same reasons it lacks standing – its own application has not even been tentatively approved." FDA Mot. at 18. In addition, the FDA argues, "determination of Ranbaxy's eligibility for exclusivity will necessarily be intensely fact-driven . . . . Mylan's claims thus raise issues that are not 'purely legal,' and that require FDA's further factual resolution." Id. at 19.

Plaintiffs, on the other hand, contend that "Matrix's ANDA is on a clear and reliable path to approval," rendering their claims ripe for judicial review. Plfs. Opp. at 5. In support, they allege that "Plaintiffs have not been informed by FDA of 'any open deficiencies with the Matrix ANDA.'" Id. at 8 (quoting Declaration of W. Talton, ¶ 11 (attached to Plfs.' Mot. for P.I.) (filed under seal)). Citing an FDA memo, Plaintiffs allege: "[redacted] The last questions that FDA posed have been answered. FDA promises in its unsworn Exhibit D and in its brief that it is conducting a review of Matrix's ANDA and other atorvastatin ANDAs in as expeditious a manner as possible, but it

has not yet issued tentative approvals on any of the atorvastatin ANDAs." Plfs. Opp. at 8 (citing Exhibit D to FDA's Motion to Dismiss, Memorandum from Keith O. Webber, Acting Director, Office of Generic Drugs, to Matrix Laboratories LTD, re: Status of ANDA Review (April 1, 2011) (filed under seal).

A review of this memorandum, however, reveals that Plaintiffs' characterizations are too sanguine. [redacted] They cannot, however, so represent with any confidence to the Court. Continued uncertainty therefore remains as to if and when Plaintiffs' ANDA will be ready for approval, be it tentative or final.

Two D.C. Circuit cases, Pfizer, 182 F.3d 975, and Teva v. Sebelius, 595 F.3d 1303, are instructive for evaluating when a claim involving a generic drug manufacturer's pending ANDA is ripe for review. In Pfizer, the FDA accepted for review an ANDA petition submitted by Mylan for a generic version of Procardia XL®. 182 F.3d at 977. Pfizer challenged the FDA's acceptance of Mylan's ANDA for review. In finding a lack of subject matter jurisdiction, the Court of Appeals applied the maxim that a "'claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated.'" Id. at 978 (quoting Texas, 523 U.S.

at 300). Pfizer thus could not challenge the agency's action of accepting Mylan's ANDA for review:

> The decision to accept Mylan's ANDA for processing as a pharmaceutical equivalent to Procardia XL® is, however, merely the first step in the agency's approval process. The critical fact remains that the FDA may never approve Mylan's application—whether because it decides in the end that the dosage form of Mylan's drug is different from that of Procardia XL® or for some entirely different reason, such as a lack of bioequivalence. Therefore, 'depending upon the agency's future actions . . . review now may turn out to have been unnecessary' and could deprive the agency of the opportunity to apply its expertise and to correct any mistakes it may have made.

Id. (quoting Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 736 (1998)).

At the other end of the ripeness spectrum, Teva v. Sebelius did not involve such factual uncertainty, and the D.C. Circuit distinguished it from Pfizer on this ground. Teva had already received tentative approval for its ANDA, and the Court observed: "The absence of any colorable factual dispute in Teva's case compels a different outcome from Pfizer. The FDA makes no suggestion that any possible deficiency or uncertainty in Teva's ANDA could thwart final approval." Id. at 1309. Rather, "the substantive issues Teva raise[d were] undoubtedly 'purely legal' in the relevant sense." Id. at 1308.

The posture of the case here more closely resembles Pfizer than Teva v. Sebelius. Factual questions exist with respect to not only the status of Plaintiffs' ANDA, but also to Ranbaxy's eligibility for exclusivity. The FDA contends that "FDA's determination of Ranbaxy's eligibility for exclusivity will necessarily be intensely fact-driven, entailing, among other things, an evaluation of whether the data in Ranbaxy's atorvastatin application are unreliable." FDA Mot. at 19. Plaintiffs do not appear to materially dispute this contention, asserting: "Neither Ranbaxy nor FDA denies that the AIP applies to Ranbaxy's atorvastatin ANDA. If it does, and if Ranbaxy cannot establish that the data in that ANDA are reliable, the

application should be withdrawn and Ranbaxy should not be granted 180-day marketing exclusivity for atorvastatin." Plfs. Opp. at 3 (emphasis added). It appears, as the record stands now, that both of these are open factual questions that the FDA needs to determine. This Court should not prematurely intrude in that process, but rather afford "the agency . . . the opportunity to apply its expertise." Pfizer, 182 F.3d at 978.

b. Final Agency Action

The FDA additionally argues that "the exclusivity issue is not fit for review because there has been no final agency action." FDA Mot. at 19. Although addressing this in the context of standing rather than ripeness, Plaintiffs respond that "[f]inal agency action, under the circumstances presented here, is not required . . . ." Plfs. Opp. at 5. The Court disagrees, as did another district court in a similar case three years ago.

Hi-Tech Pharmacal Co., Inc. v. FDA, 587 F. Supp. 2d 1 (D.D.C. 2008), involved a generic drug manufacturer that both was a first filer and had received tentative approval. Id. at 5-6. Hi-Tech sought a declaratory judgment that it was entitled to 180 days of marketing exclusivity and a preliminary injunction enjoining the FDA from granting final approval to Hi-Tech's competitors. Id. at 6-7. Hi-Tech, like Plaintiffs here, alleged that the FDA had, in violation of the APA, unreasonably failed to act – in this case, by declining to make a decision regarding Hi-Tech's entitlement to exclusivity prior to the date any generic manufacturer (including itself) could first receive final approval. Id. at 7, 9. In denying Hi-Tech's motion for a preliminary injunction, the court concluded that Hi-Tech was unlikely to succeed on the merits of its APA claim because, since there had been no final agency action, Hi-Tech's claims were not yet ripe. Id. at 10.

Contrary to Plaintiffs' argument, final agency action – or its functional equivalent – is a prerequisite to judicial review, even for claims brought under § 706(1) of the APA for

unreasonable delay. As the Hi-Tech court explained, "[A] claim under Section 706(1) 'can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take.'" Id. at 9 (emphasis in original) (quoting Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 64 (2004)). After evaluating Hi-Tech's claim, the court concluded, "[R]esolving Hi-Tech's entitlement to exclusivity is not a discrete agency action that the FDA is required to take, pursuant to statute or regulation, by a time certain." Id. at 9. If a plaintiff cannot seek judicial review of the FDA's failure to decide the plaintiff's own entitlement to exclusivity by a certain time, Plaintiffs in this case, who seek to force an FDA decision on a competitor's entitlement to exclusivity, certainly cannot present a claim that is fit for review. Similarly, while the Hi-Tech court recognized that a plaintiff may assert a claim when an agency's failure to act "is the functional equivalent of final agency action," the "FDA's failure to act with respect to the issue of exclusivity does not amount to final agency action here." Id. at 10.

The Hi-Tech court also related the requirement of final agency action back to the question of the plaintiff's harm, stating: "Quite clearly, the FDA's inaction has not had the same impact on Hi-Tech as an express denial of relief (*i.e.*, a finding of forfeiture), which would presumably determine the scope of the parties' rights. In fact, the FDA's inaction has had just the opposite effect, as Hi-Tech asserts that the FDA's failure to act perpetuates 'unnecessary uncertainty' as to the parties' rights." Id. As the FDA here, too, has not made a decision regarding exclusivity (either in Plaintiffs' favor or Ranbaxy's), the current state of uncertainty similarly translates into a lack of ripeness. Plaintiffs have thus not stated a claim of unlawful failure to act that is fit for review under either § 706(1) or § 706(2).

2. Hardship

As to the second ripeness factor – hardship to the parties of withholding court consideration – the D.C. Circuit "has frequently suggested that hardship is not a *sine qua non* of ripeness." Teva v. Sebelius, 595 F.3d at 1310. A brief inquiry is nevertheless appropriate.

Plaintiffs allege they will suffer financial losses as a consequence of not knowing whether Ranbaxy will be entitled to a period of atorvastatin marketing exclusivity because they cannot knowledgeably prepare for a potential launch of their generic drug on June 28, 2011. As discussed above, however, Plaintiffs' ability to launch on June 28 is dependent not only on whether Ranbaxy is entitled to 180 days of marketing exclusivity, but also on whether Plaintiffs' own ANDA has been approved. Until the FDA approves (at least tentatively) Matrix's ANDA, any hardship Plaintiffs might suffer as a result of the FDA's failure to decide the exclusivity issue is hypothetical.

By dismissing Plaintiffs' claims now, the Court does not foreclose the possibility that Plaintiffs may seek a judicial remedy at a future date – *e.g.*, when Plaintiffs' claims are truly fit for review. See Pfizer, 182 F.3d at 979 ("This case might nonetheless be ripe if the FDA's acceptance of Mylan's ANDA for processing somehow foreclosed Pfizer's right ever to get meaningful judicial review, but it does not. If the FDA eventually approves Mylan's application, Pfizer may then challenge the reasons underlying its final decision . . . ."). As the FDA points out, "Nothing prevents Mylan from seeking judicial recourse if and when FDA renders a final exclusivity decision that is not to Mylan's liking." FDA Mot. at 22. This is not to say, however, that an approval of Ranbaxy's exclusivity period would necessarily confer standing on Plaintiffs if their own ANDA had not progressed.

In addition to a lack of standing, therefore, the Court finds that Plaintiffs' claims are not ripe for judicial review. This alternate ground also mandates that the Court grant the FDA's

Motion to Dismiss under Rule 12(b)(1). Because the Court finds that it lacks subject matter jurisdiction to hear Plaintiffs' claims, analysis under Rule 12(b)(6) is not warranted.

IV. Conclusion

The Court, therefore, ORDERS that:

1) The Defendants' Motions to Dismiss are GRANTED;

2) Plaintiffs' Motion for Preliminary Injunction is DENIED; and

3) Plaintiffs' Complaint is DISMISSED for lack of subject matter jurisdiction.

SO ORDERED.

/s/ *James E. Boasberg*
JAMES E. BOASBERG
United States District Judge

Date: May 2, 2011