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
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
Defendant.	)	

INTERVENOR-DEFENDANT RANBAXY LABORATORIES LIMITED'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Mylan Pharmaceuticals, Inc. and Matrix Laboratories Ltd.'s (collectively "plaintiffs") lawsuit and motion for preliminary injunction, far from the effort to promote consumer well-being that plaintiffs claim it to be, is in fact a self-serving effort to force the United States Food and Drug Administration ("FDA") into a premature decision on a question of great importance. That question is whether Intervenor-Defendant Ranbaxy Laboratories, Ltd. ("Ranbaxy") is entitled to FDA approval of its Abbreviated New Drug Application ("ANDA") for atorvastatin, and whether Ranbaxy should receive 180 days of generic marketing exclusivity – the statutory incentive designed to encourage generic companies to challenge brand company patents. Ranbaxy is entitled to such exclusivity for generic atorvastatin, having expended millions of dollars to challenge successfully Pfizer's patents for Lipitor®, the largest selling drug in the United States in terms of dollar revenue.

FDA has not yet issued a decision on whether to approve Ranbaxy's ANDA or to award the company exclusivity, and there is no final agency action for the Court to review under the Administrative Procedure Act ("APA"). Plaintiffs therefore seek to short-circuit the FDA decision-making process so that they can enter the generic atorvastatin market free from the constraints of Ranbaxy's hard-earned exclusivity. Plaintiffs, however, cannot meet the requirements for judicial review under the APA for their claims, and their action is premature. In short, the Court lacks subject matter jurisdiction over plaintiffs' claims. Plaintiffs' complaint should be dismissed, and their motion for preliminary injunction should be denied for failure to show a likelihood of success on the merits. Plaintiffs also fail to meet the other requirements for a preliminary injunction.

Ranbaxy has fought hard for, and believes it has earned the right to 180 days of marketing exclusivity for atorvastatin. Plaintiffs, by contrast, have done nothing to facilitate

generic entry into the atorvastatin market other than trying to force FDA to deny Ranbaxy exclusivity, and thereby seeking to undermine the incentive created by Congress for generic companies to challenge brand company patents. Plaintiffs have no right, under the Federal Food, Drug and Cosmetic Act ("FFDCA") or otherwise, to force FDA to make a decision on Ranbaxy's application or exclusivity before such time as it is appropriate to do so.

STATUTORY AND REGULATORY BACKGROUND

A. The Hatch-Waxman Amendments

The Hatch-Waxman Amendments to the FFDCA ("Hatch-Waxman") establish the regime for generic drug approvals in the United States. Among other things, these provisions are intended to encourage generic competition to provide lower cost versions of branded drugs as early as possible. *See, e.g., Abbott Labs., Inc. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990), *citing* H.R. Rep. No. 98-857, pt. 1, at 14, 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648; *see also* 54 Fed. Reg. 28872, 28874 (July 10, 1989). A crucial component of the Hatch-Waxman regime is its provisions for the identification of brand company patents that cover specific drugs, and its award of 180 days of marketing exclusivity to the first generic company to challenge successfully a brand company patent that might otherwise block competition against a particular approved brand drug.

1. New Drugs and Patent Information Requirements

Before marketing a new drug in the United States, a manufacturer must submit to FDA and obtain agency approval of a New Drug Application ("NDA"). An NDA must include information on each patent that claims the drug or a method of using the drug that is the subject of the NDA. 21 U.S.C. § 355. Once approved, such drugs generally are referred to as "brand name drugs" because they are marketed under a trade name or trademark for the drug product.

FDA publishes the patent information submitted by the brand name drug manufacturers in *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the "Orange Book." 21 U.S.C. § 355(b)(1). The Orange Book includes an index of drug products by trade or established name as well as drug patent and exclusivity information. 21 C.F.R. § 314.53.

2. Generic Drugs and Patent Certification Requirements

A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark for the drug product. Generic drugs are frequently cited as an important component of efforts to control healthcare costs because generic drugs are typically far less expensive than brand name drugs.[1]

The introduction of a generic drug as an alternative to a brand name drug typically results in a dramatic reduction in the brand name drug's market share, particularly within the first six months. *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), http://www.cbo.gov/fptdocs/6xx/doc655/pharm.pdf.

Before marketing a generic drug in the United States, a manufacturer must submit to FDA and obtain agency approval of an ANDA. 21 U.S.C. § 355(a). An ANDA applicant must show that its generic drug is the same as the approved brand drug referenced in the ANDA (the "reference listed drug"), including that the generic drug for which approval is sought is bioequivalent to the previously approved brand name drug. 21 U.S.C. § 355(j)(8)(B).

[1] *See, e.g.*, Press Release, Generic Pharmaceutical Association, *Generic Pharmaceuticals Saved $734 Billion over Last Decade* (May 7, 2009), http://gphaonline.org/media/press-releases/2009/generic-pharmaceuticals-saved-734-billion-over-last-decade (finding generic medicines saved the American health care system more than $734 billion in the last decade (1999-2008) with approximately $121 billion in savings in 2008 alone). Generic drugs represent an increasing portion of the medicines used in the United States. Seventy percent of prescriptions in this country are today filled with generics. Susan Okie, *Multinational Medicines – Ensuring Drug Quality in an Era of Global Manufacturing*, 361 New Eng. J. Med. 737, 738 (2009). By contrast, in 1984, the year that Hatch-Waxman was enacted, approximately 18.6 percent of prescriptions were filled with generics. *See, e.g.*, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 19-94 (2007).

Bioequivalence is not enough for approval, an applicant also must meet a number of other statutory and regulatory criteria. 21 U.S.C. § 355(j)(4); 21 C.F.R. § 314.105(c).

In addition, an ANDA applicant seeking FDA approval for a generic version of an approved brand name drug product must file one of four certifications with FDA for each patent listed in the Orange Book as claiming the brand name drug. These certifications are described as paragraph I, II, III or IV certifications. A paragraph I certification states that no patent information has been filed; a paragraph II certification states that the patent has expired; and a paragraph III certification states the ANDA applicant will not market its product until the date on which the patent will expire. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(III). Of particular relevance to this case is a paragraph IV certification, which states that the patent claiming the brand name drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.50(i).

If an ANDA applicant submits a paragraph IV certification to FDA, it is required to notify the patent owner and the holder of the approved NDA of its intent to seek approval of its ANDA and to compete with the brand name drug manufacturer before expiration of the listed patent. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.52(a). The filing of an ANDA with a paragraph IV certification is deemed to be an act of infringement, and if the brand name drug manufacturer sues for patent infringement within 45 days of receiving notice of the paragraph IV certification, approval of the ANDA is stayed for 30 months. 35 U.S.C. § 271(e)(2); 21 U.S.C. § 355(j)(5)(B)(iii).

In order to encourage generic manufacturers to subject themselves to the risk and expense of patent litigation, Hatch-Waxman rewards the first ANDA applicant to file an ANDA with a

paragraph IV certification, relating to a patent for the reference listed drug, with 180 days of marketing exclusivity, during which it is the only ANDA applicant allowed to market a generic version of the brand name product. 21 U.S.C. § 355(j)(5)(B)(iv).[2]

In the normal course, the Agency's Office of Generic Drugs ("OGD") conducts its review of all pending applications for a particular drug product so as to ensure that any applications that qualify for approval are reviewed prior to the date on which a generic may first go to market. Mylan does not allege, and Ranbaxy believes it cannot allege, that the Agency will not follow its policy with regard to atorvastatin. On the first date that a generic may be marketed, the Agency will so inform all applicants that qualify for approval. If the applicant is blocked by another applicant's exclusivity, the Agency also will notify each applicant of that fact. Any applicant that disagrees with FDA's decision may challenge FDA's decision in court at that time.

B. The Application Integrity Policy

The Application Integrity Policy ("AIP") is a policy that FDA developed to ensure the reliability of data called into question by alleged wrongful acts of an applicant. In such cases, FDA will conduct an investigation to identify all instances of wrongful acts, if any, and to determine the extent to which wrongful acts may have affected approved or pending applications. As a result of its investigation, FDA may refuse to approve or withdraw approval for applications. *See* Compliance Policy Guide § 7150.09, published at 56 Fed. Reg. 46191, 46199-200 (Sept. 10, 1991). In short, the invocation of the AIP is the start of an investigative process in which both FDA and the applicant participate, not a final determination or finding as

[2] Ranbaxy filed its ANDA prior to the effective date of the Medicare Modernization Act of 2003 ("MMA"), which amended Hatch-Waxman. Accordingly, Ranbaxy's ANDA is governed by the pre-MMA provisions of Hatch-Waxman.

to any specific application. At the conclusion of an AIP investigation, FDA may determine that a particular application is or is not associated with a wrongful act.

The Agency has invoked its AIP process as to one of Ranbaxy's facilities. No other Ranbaxy site is subject to the AIP process. The AIP process has not impeded the approval of ANDAs from other Ranbaxy sites.

FACTUAL BACKGROUND

Pfizer, Inc. ("Pfizer") holds the FDA approval for brand name versions of atorvastatin, which it markets as Lipitor®. In August 2002, Ranbaxy filed an ANDA for atorvastatin. As part of its ANDA, Ranbaxy was required to submit a paragraph I, II, III or IV certification for each of the Pfizer patents listed in the Orange Book at that time. When Ranbaxy originally filed its ANDA, it included paragraph IV certifications for three of the five patents listed in the Orange Book, and paragraph III certifications for the remaining two patents. The latest of these patents did not expire until 2017. Ranbaxy's challenge to these three patents was successful; Pfizer did not sue Ranbaxy on the patents for which it had filed paragraph IV certifications. By virtue of this successful challenge, FDA could approve Ranbaxy's ANDA six years sooner than it could have approved a generic applicant.

Subsequently, Ranbaxy amended its paragraph III certifications for the 4,681,893 patent (the "'893 patent") and the 5,273,995 patent (the "'995 patent") and changed them to paragraph IV certifications, in January and February 2003, respectively. In March 2009, on the same day that Pfizer listed U.S. Patent No. RE 40,667, which is a reissue of the '995 patent, Ranbaxy filed a paragraph IV certification for that patent. Accordingly, since February 28, 2003, Ranbaxy has properly maintained paragraph IV certifications for all unexpired patents listed for Lipitor® in the Orange Book.

Starting in 2003, and as envisioned by Hatch-Waxman, Ranbaxy and Pfizer squared off in litigation regarding certain of the Pfizer patents for Lipitor®, to which Ranbaxy had filed paragraph IV certifications. Ranbaxy's persistence and investment paid off, with the United States Court of Appeals for the Federal Circuit determining that the only asserted claim of one of Pfizer's patents was invalid; therefore, this patent could not be used to block generic competition against Lipitor®. The result of this decision was a settlement between Pfizer and Ranbaxy, pursuant to which Ranbaxy may market its generic atorvastatin product on November 30, 2011. As a reward for being the first filer of paragraph IV certifications for the Pfizer patents, Ranbaxy is eligible to receive generic exclusivity as early as November 30, 2011, when it may first market its atorvastatin product under the Pfizer license.

Because Matrix Laboratories Ltd. ("Matrix") did not file an ANDA for atorvastatin until 2008, six years after Ranbaxy first challenged the Pfizer patents, Matrix and its business partner Mylan Pharmaceuticals, Inc. ("Mylan") are subject to Ranbaxy's exclusivity. Mylan may not market its product until Ranbaxy's 180 days of exclusivity are over.

The fact that plaintiffs may not obtain approval of, or market their atorvastatin product until Ranbaxy's exclusivity is over does not mean that there will be no generic competition until Ranbaxy's ANDA is approved or rejected. Another generic competitor, Watson Pharmaceuticals, Inc. ("Watson") will be able to market a generic atorvastatin product on November 30, 2011, and perhaps earlier, regardless of whether Ranbaxy's ANDA is approved. Exhibit A, Declaration of David A. Buchen ("Buchen Decl.") ¶ 4.

* * *

On February 25, 2009, FDA sent a letter to Ranbaxy informing it that the Agency was applying the AIP to Paonta Sahib, one of Ranbaxy's manufacturing sites. In that letter, FDA

stated it would conduct a validity assessment of the data and information that was generated at the site and relied on in Ranbaxy's applications. *See* Decl. of Karla L. Palmer in Supp. of Pls.' Mot., Ex. C (AIP Letter to Ranbaxy) at 5. Ranbaxy knows of no data issue associated with the atorvastatin ANDA that should bear on its approvability or exclusivity. In fact, Ranbaxy has disputed allegations in the AIP letter, while, at the same time cooperating fully with FDA in the AIP data assessment process. FDA has not completed the AIP process, nor has it refused to approve or withdrawn approval of any application.

ARGUMENT

I. PLAINTIFFS' COMPLAINT SHOULD BE DISMISSED, AND ITS MOTION FOR A PRELIMINARY INJUNCTION SHOULD BE DENIED.

FDA has not yet completed the AIP process, nor has the Agency rendered any decision on Ranbaxy's ANDA or on the issue of exclusivity. Plaintiffs, however, seek to force FDA's hand in an effort to hasten their own ability to market generic atorvastatin and have alleged improper inaction by FDA on Ranbaxy's ANDA. Plaintiffs' claims of agency inaction require them to demonstrate either that the agency has "unreasonably delayed" under Section 706(a)(1), or that its inaction was the functional equivalent of final agency action. Plaintiffs can do neither. Accordingly, their claims are premature and are not subject to judicial review. On these grounds alone, the Complaint should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1).

For these same reasons, plaintiffs' motion for preliminary injunction should be denied for failure to demonstrate likelihood of success on the merits. *See Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 7 (D.D.C. 2008) ("Indeed, '[w]ithout any probability of prevailing on the merits, the Plaintiffs' purported injuries, no matter how compelling, do not justify preliminary injunctive relief.'") (citation omitted). Plaintiffs fare no better on the remaining preliminary

injunction factors. Indeed, each of these three factors weigh against the issuance of a preliminary injunction in this case.

A preliminary injunction is "an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion." *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). District courts in this Circuit have applied an even higher standard when plaintiffs seek, as they have in this case, a preliminary injunction that does not merely maintain the status quo, but instead alters it, *i.e.*, a mandatory injunction.[3] *See Kotz v. Lappin*, 515 F. Supp. 2d 143, 151-52 (D.D.C. 2007) ("[B]ecause the plaintiff seeks a mandatory injunction, rather than to merely maintain the status quo, he must demonstrate beyond the familiar 4-part test for injunctive relief, that he is 'clearly' entitled to the relief he seeks or 'extreme or very serious damage will result.'") (citations omitted). *King v. Leavitt*, 475 F. Supp. 2d 67, 71 (D.D.C. 2007) (same). Here, plaintiffs are seeking to require FDA to act to deny Ranbaxy's ANDA and/or to strip Ranbaxy of generic exclusivity, not to maintain the status quo. Plaintiffs cannot satisfy their heavy burden in this case.[4]

[3] The D.C. Circuit has "neither adopted nor rejected" a heightened standard for mandatory preliminary injunctions. *Mylan Labs., Inc. v. Leavitt*, 495 F. Supp. 2d 43, 47 n.5 (D.D.C. 2007) (citing *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 834 n.31 (D.C. Cir. 1984)).

[4] Plaintiffs' motion for preliminary injunction should be denied for an additional reason; it is a wolf in sheep's clothing and seeks relief that is not preliminary in nature at all. Rather, the relief sought by plaintiffs amounts to a mandatory injunction that would effectively dispose of this action. Plaintiffs' proposed order states: "Defendant FDA will issue a decision [within ___ days] regarding whether Ranbaxy's ANDA for atorvastatin calcium tablets is eligible for a period of 180-day marketing exclusivity." Proposed Order 2; compare to Compl. 23-24 (requesting that FDA be ordered to deny Ranbaxy's ANDA and approve plaintiffs' ANDA). It appears that plaintiffs have backed away from the even more aggressive relief pled in their complaint, but all the same seek final relief through their motion for preliminary injunction. It is inappropriate for the Court to award final relief on a preliminary injunction motion, and the Court should deny the motion for this reason as well.

A. Plaintiffs Have Not Demonstrated that Their Claims Are Subject to Judicial Review And, for that Reason, Have Failed to Demonstrate A Likelihood of Success on the Merits.

Plaintiffs seek extraordinary relief in this case. They ask the Court to truncate FDA's decisionmaking process, and to decide, in lieu of the Agency, that Ranbaxy's ANDA should be denied and that it should be stripped of its hard-earned 180-day marketing exclusivity. *See* Compl. 22-23. Without citing a single case in support, or analyzing the relevant legal standards, plaintiffs assert that judicial review of their claims is appropriate under sections 706(a)(1) and (a)(2) of the APA. Pls.' Br. 25. The bar for judicial review under the APA is high, and plaintiffs have not come close to meeting their burden under either of the sections they identify.

In order for the Court to compel FDA to reach a decision on Ranbaxy's ANDA and its eligibility for exclusivity under Section 706(a)(1) of the APA, plaintiffs must demonstrate that FDA "unlawfully withheld or unreasonably delayed" acting on Ranbaxy's ANDA. 5 U.S.C. § 706. Courts wade carefully into the waters of agency delay and "are reluctant to upset existing agency priorities, unless the delay is 'egregious.'" *Cobell v. Norton*, 240 F.3d 1081, 1096 (D.C. Cir. 2001) (citing *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 79 (D.C. Cir. 1984)). Further, "[a]n agency's own timetable for performing its duties in the absence of a statutory deadline is due 'considerable deference.'" *Id.* (citing *Sierra Club v. Gorsuch*, 715 F.2d 653, 658 (D.C. Cir. 1983)).

Courts consider the following four factors in reviewing an unreasonable delay claim:

> First, 'the court should ascertain the length of time that has elapsed since the agency came under a duty to act.' . . . Second, 'the reasonableness of the delay must be judged 'in the context of the statute' which authorizes the agency's action.' . . . Third, the court must examine the consequences of the agency's delay. . . . Finally, the court should give due consideration in the balance to 'any plea of administrative error, administrative convenience, practical difficulty in carrying our a legislative mandate, or need to prioritize in the face of limited resources.'

Cobell, 240 F.3d at 1096 (citing *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992)). Plaintiffs fail to satisfy any of these factors.

First, plaintiffs cite to no statutory or regulatory provision that compels the Agency to respond to their informal letter requests within any particular timeframe or to make a decision on Ranbaxy's ANDA "now." Pls.' Br. 19. The agency therefore has not yet come under a duty to act, much less failed to act within the timeframe established by that duty. Second, plaintiffs cannot even allege that there will be a delay in approving either Ranbaxy's or plaintiffs' application, let alone whether any delay would be unreasonable. Third, as discussed below in Section I.B, Mylan has not suffered irreparable harm as a result of FDA's continuing process under the AIP. On the other hand, were the Court to truncate the Agency's review, substantial harm would befall both Ranbaxy and FDA. *See* Section I.C. Finally, FDA's own weighing of its competing administrative concerns should be given great weight here. *See In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("In short, we have no basis for reordering agency priorities. The agency is in a unique – and authoritative – position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.").[5]

Plaintiffs also allude, again without analysis, to a second potential claim under the APA, suggesting that FDA's inaction on Ranbaxy's atorvastatin application somehow constituted final agency action and is therefore reviewable by this Court under Section 706(a)(2) of the APA. *See* Pls.' Br. 25. Section 551(13) of the APA defines agency action to include a "failure to act." 5 U.S.C. § 551(13). Agency inaction, however, rises to the level of final agency action under the

[5] Plaintiffs have jumped the gun in filing this litigation. Indeed, on March 17, 2011, just one day before they filed their Complaint, plaintiffs sent yet another letter to FDA. Plaintiffs gave FDA no opportunity to respond and instead filed suit. Had plaintiffs wanted to obtain an answer from FDA within a set timeframe, they could have filed a citizen petition, to which the Agency would have been required to respond within 180 days. 21 C.F.R. 10.30(e)(2). They elected not to do so.

APA only if it "amounts to consummated agency action . . . notwithstanding the fact that the agency did nothing . . . ." *Hi-Tech Pharmacal Co., v. FDA*, 587 F. Supp. 2d 1, 9 (D.D.C. 2008) (internal quotation marks and citation omitted). Indeed, "[t]he D.C. Circuit has stated that APA review of an agency's failure to act is appropriate when the challenged 'inaction may represent effectively final agency action that the agency has not frankly acknowledged.'" *Id.* at 10 (citing *Sierra Club v. Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987)); *see also id.* ("Judicial review of an agency's failure to act under Section 706(2) is authorized, then, 'when administrative inaction has the same impact on the rights of the parties as an express denial of relief.'") (citations omitted).

In this case, FDA's failure to act on Ranbaxy's ANDA now is not the functional equivalent of FDA having approved Ranbaxy's application and upheld its exclusivity, though Ranbaxy believes that is the result compelled under the governing statute, regulations and precedent. Plaintiffs do not argue to the contrary. They complain instead of the uncertainty caused by FDA's failure to make a decision, and not that the Agency, by failing to act on Ranbaxy's ANDA, has already decided these issues against them. *See* Mylan Br. at 2 ("FDA has unreasonably and unlawfully failed to issue a decision."); 3 ("[U]ntil FDA acts – one way or the other – manufacturers cannot prepare for a commercial launch . . . ."); 14 ("FDA has refused to disclose any information concerning the status of Ranbaxy's ANDA."); 23 ("[I]t is impermissible for FDA to refuse to disclose whether the Ranbaxy ANDA for atorvastatin is covered by the AIP, and, if so, whether FDA will reject that application"). Accordingly, plaintiffs do not contend that through its inaction FDA has rendered a decision affecting their (or Ranbaxy's) rights. *See Hi-Tech* at 587 F. Supp. 2d at 10 ("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."). As such, FDA's inaction is not tantamount to final agency action under the APA and is not reviewable by this Court under Section 706(a)(2) of the APA.

Finally, the authorities cited by plaintiffs at pages 19-24 of its brief, and the arguments they advance on the substantive question of whether FDA should, when it ultimately makes its decision, deny Ranbaxy's ANDA or strip it of exclusivity, do not support their claims under Section 706(a)(1) and (a)(2). FDA has not made any final factual determinations regarding Ranbaxy's atorvastatin ANDA, which would support a denial of the application under Section 355(j)(4). If the Agency were to do so, Ranbaxy would have a right to judicial review. *See* 21 U.S.C. § 355(j)(5)(A) and (E) (if FDA "decides to disapprove an application," then the Agency "shall give the applicant notice of an opportunity for a hearing . . . on the question of whether such application is approvable"). The AIP letter did not and cannot deprive Ranbaxy of its rights, including its rights to review. Mylan cannot seriously urge this Court to order the Agency to act in a way that deprives Ranbaxy of its statutory rights. Ranbaxy is entitled to an individualized review of its application under the FFDCA and the AIP, and plaintiffs may not short-circuit the process by which this review takes place.[6]

B. Mylan Has Not Demonstrated Irreparable Harm.

The irreparable harm prong of the preliminary injunction analysis "erects a very high bar for a movant." *Coal. for Common Sense in Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.C. Cir. 2008) (citation omitted). To demonstrate irreparable harm, the injury "'must

[6] The AIP is nothing more than an FDA policy. It was neither enacted by Congress nor promulgated through notice and comment rulemaking, and it cannot function to expand or abrogate the FFDCA. The FFDCA requires findings specific to the ANDA under review to disapprove an application. The AIP cannot and does not modify the statutory standard. The AIP simply creates a process for conducting a review intended in part to determine whether such a finding should be made as to a specific application.

be both certain and great; it must be actual and not theoretical.'" *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). It is "well settled that economic loss does not, in and of itself, constitute irreparable harm." *Id.* Further, "to successfully shoehorn potential economic loss into a showing of irreparable harm, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence." *Coal. For Common Sense in Gov't Procurement*, 576 F. Supp. 2d at 168. Plaintiffs have failed to satisfy this "very high bar."

First, the harm alleged by plaintiffs is speculative. Plaintiffs admit that they may only market their atorvastatin product "subject to FDA regulatory approval." Plaintiffs' Br. at 26. Despite this admission that they have not yet obtained tentative approval for their ANDA, plaintiffs still argue that they will suffer irreparable injury if FDA does not issue a decision on Ranbaxy's ANDA. Such an assertion is baseless. Without a tentative approval, plaintiffs cannot demonstrate any "certain and great injury." There is no guarantee that plaintiffs will ever obtain approval of their ANDA or market an atorvastatin product, let alone that they would be able to do so as early as June 2011. Even if, however, plaintiffs had an approval, their economic damages would still be speculative. As plaintiffs allege, there are at least six other atorvastatin ANDAs pending before FDA. Compl. ¶ 5. Where those other applicants are in the approval queue affects the level of competition plaintiffs would face and the amount of product they would need to manufacture for any launch. Plaintiffs have failed to factor this consideration into their calculations.

Second, the speculative harm alleged by plaintiffs is purely economic. Plaintiffs have not adequately demonstrated that the harm it claims will "cause extreme hardship" to Mylan or that it threatens the "very existence" of the company. Plaintiffs' claim that "significant" revenue

would be lost (Pls.' Br. at 30) – even if it were quantifiable (which it is not, given that plaintiffs have no way of knowing with whom they might be sharing the market) – is insufficient to demonstrate that their purely economic harm is irreparable.

Third, *Mova Pharmaceutical Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), which is cited by plaintiffs in support of their irreparable harm argument, is inapposite. In that case, the Court held that depriving Mova of its 180 days of statutory exclusivity would cause injury to Mova. *Id.* at 131. Plaintiffs here have no claim to 180-day exclusivity, let alone any claim that they are being wrongfully deprived of that statutory right. To the contrary, it is Ranbaxy who stands to suffer irreparable harm if it is erroneously stripped of its exclusivity.

Finally, the lack of any actual or imminent injury to plaintiffs precludes any preliminary or permanent relief. In fact, by the time the Agency completes its process, the identity of the parties who may claim to be aggrieved could change entirely. Plaintiffs' application may be denied; some of the other pending applications may be approved, delayed or denied. This court may see a different suit or no suit at all.

C. The Balance of Harms Weighs in Favor of Ranbaxy.

The harm that would befall Ranbaxy if a preliminary injunction were issued in this case dwarfs the speculative, financial injury that plaintiffs incorrectly dub "irreparable harm." The relief sought in this case is not a preliminary injunction that would maintain the status quo. Instead, plaintiffs seek an order compelling FDA to make a decision immediately on Ranbaxy's ANDA and its entitlement to exclusivity. As a result, Ranbaxy risks being stripped prematurely of its exclusivity. The effect of the preliminary injunction could be to deprive Ranbaxy of a statutory right, *i.e.*, 180-day marketing exclusivity, to which it is entitled. This harm, in contrast to the weak "injury" put forth by Mylan, has been recognized in this Circuit, in the very case

cited by plaintiffs, to be irreparable in nature. *See Mova*, 955 F. Supp. at 131 ("depriving Mova of a 180-day statutory grant of exclusivity . . . will cause injury to Mova.").

Ranbaxy has earned its right to 180-day marketing exclusivity as a result of significant financial investment and hard-fought patent litigation, which resulted in a successful outcome – a holding by the Federal Circuit that the only asserted claim in one of Pfizer's patents was invalid and which prompted the settlement between Pfizer and Ranbaxy allowing for Ranbaxy's launch, without risk of future patent litigation on additional Lipitor® patents on November 30, 2011. Ranbaxy's efforts meet the purpose behind the Hatch-Waxman Amendments: to encourage generic manufacturers to challenge patents so that generic products may be brought to market more quickly, thereby resulting in tremendous cost savings for consumers. To strip Ranbaxy of this significant statutory benefit before FDA has had the opportunity to complete its administrative review and process would cause irreparable and incomparable harm to Ranbaxy.

Despite plaintiffs' protestations to the contrary, FDA also would suffer harm if the Court were to issue a preliminary injunction in this case. Plaintiffs are asking the Court to force the Agency to make a decision on plaintiffs' timetable. Such a ruling would be a harmful intrusion on the Agency's internal decision making process. In addition, the public interest prong of the preliminary injunction inquiry weighs against granting the requested injunction in this case because it is in the public's interest for FDA to make a decision on Ranbaxy's application only when it is ready, and no sooner. The public also benefits from a thorough and consistent application of the FFDCA. Further, there is a date certain, regardless of FDA's decision on Ranbaxy's ANDA, that consumers will have access to a cheaper, generic atorvastatin product. An authorized generic will be available on the market on November 30, 2011, little more than six months from now. *See* Ex. A, Buchen Decl., ¶ 4. This authorized generic product will be priced

significantly lower than Lipitor®. *See* Ex. A, Buchen Decl., ¶ 6. The timing of generic competition has been made possible by Ranbaxy's efforts. Forcing FDA to determine prematurely that Ranbaxy is not entitled to the benefits of its hard-earned successes in litigation would undermine incentives created by Hatch-Waxman to encourage precisely the activities that Ranbaxy undertook in this case.

CONCLUSION

For the foregoing reasons, Ranbaxy respectfully requests that the Court dismiss plaintiffs' complaint for lack of subject matter jurisdiction and deny plaintiffs' motion for preliminary injunction.

Dated: April 4, 2011

Respectfully submitted,

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