UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS INC. and MATRIX LABORATORIES LTD., Plaintiffs,	)	
v.	)	Civil Action No. 11-566 (JEB)
UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant,	)	**[REDACTED]**
and	)	
RANBAXY LABORATORIES LIMITED, Intervenor-Defendant.	)	

FEDERAL DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

DAVID J. HOROWITZ
Deputy General Counsel

RALPH S. TYLER
Associate General Counsel,
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

WENDY S. VICENTE
Associate Chief Counsel

U.S. Dept. of Health & Human Services
Office of the General Counsel
White Oak 31 Room 4562
10903 New Hampshire Avenue
Silver Spring, MD 20993

TONY WEST
Assistant Attorney General

EUGENE M. THIROLF
Director
Office of Consumer Litigation
Civil Division

ANDREW E. CLARK
Senior Litigation Counsel
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 307-0067

Dated: April 4, 2011

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

FEDERAL CASES

Page(s)

**Authorities upon which we chiefly rely are marked with asterisks*

FEDERAL STATUTES

FEDERAL REGULATIONS

FEDERAL RULES

MISC.

GLOSSARY

AIP	FDA's Application Integrity Policy. *See* "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy," 56 Fed. Reg. 46,191, 46,199-46,200 (1991); Application Integrity Policy, *available at* http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm;
ANDA	Abbreviated New Drug Application submitted under 21 U.S.C. § 355(j)
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 *et seq*.)
Hatch-Waxman Amendments	The Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282
MMA	The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003)
NDA	New Drug Application filed under 21 U.S.C. § 355(b)
180-day exclusivity	Under the applicable 2002 version of the statute, a period of marketing exclusivity granted to an applicant who files the first paragraph IV certification to each listed patent. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2002)
Paragraph IV certification	A certification made by an ANDA applicant under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that a patent listed by the NDA holder is invalid or not infringed

INTRODUCTION

Plaintiff Mylan Pharmaceuticals Inc., together with its corporate sibling Matrix Laboratories Ltd. (collectively, "Mylan"), hopes to market a generic version of Lipitor, one of the most prescribed drugs in the world. Significant exclusivity is set to expire on June 28, 2011, but no generic applicant – including Mylan – has any certainty it will resolve all outstanding scientific and/or technical issues so that its application will be ready for approval by that date. Mylan's mere anticipation that it may be approvable does not confer standing, nor does it make Mylan's claims ripe for this Court's review.

Notwithstanding the lack of certainty about whether or when all remaining scientific and/or technical issues will be resolved so that its own application may be approved, Mylan seeks to eliminate a *different* potential barrier to the possible marketing of its product. Mylan surmises that another generic manufacturer, Intervenor-Defendant Ranbaxy Laboratories Ltd. ("Ranbaxy"), is eligible for 180 days of marketing exclusivity as the first generic applicant to challenge the patents for Lipitor, and that Ranbaxy's application cannot be approved because it may contain unreliable data. Mylan seeks to compel the Food and Drug Administration ("FDA") to promptly take enforcement action against Ranbaxy to strip it of any exclusivity – and make a public announcement about the status of a confidential pending application – all to clear the way for Mylan to take preliminary steps to prepare for the early generic market entry it desires.

But under settled legal principles, FDA cannot be compelled to take enforcement action, and it has unreviewable discretion to decide when and whether to exercise its enforcement authority in a given case. *See Heckler v. Chaney*, 470 U.S. 821, 829 (1985). Nor has FDA "unreasonably delayed" making an exclusivity decision because no statute obligates FDA to decide or announce what applicants may or may not be eligible for exclusivity before an

application is ready for approval. Under the Administrative Procedure Act ("APA"), a claim for unreasonable delay will lie only when an agency has illegally withheld or unreasonably delayed a discrete action that it is *required* to take, and that is not the case here. Mylan's desire to facilitate its business planning does not trump settled principles of justiciability and review, and its allegations are insufficient to establish subject matter jurisdiction or state a claim under the APA.

Mylan has also failed to establish that it will suffer certain, great, and irreparable injury in the absence of a preliminary injunction. Mylan alleges that it will cost it "tens of millions of dollars between now and the end of June, 2011" to prepare adequately for an uncertain launch as early as June 28, 2011. PI Mem. at 16. But such investment expenditures in the hope of an approval do not constitute irreparable harm. Both plaintiffs are subsidiaries of Mylan, Inc., one of the world's largest generic drug companies, with a diverse product line and several billions of dollars in annual revenue.[1] Although the prospect of being an early generic entrant for Lipitor is certainly worth a great deal of money, Mylan nowhere alleges that any harm it might suffer in the absence of a preliminary injunction would threaten or even seriously injure its business. Mylan's speculative claim of potential monetary loss simply does not rise to the level of irreparable harm sufficient to support a request for exigent equitable relief.

The balance of harms also weighs against the entry of preliminary relief because Mylan's desire for better business planning information does not outweigh FDA's interest in the thoughtful and careful exercise of its enforcement discretion and the timing of its regulatory decisionmaking without judicial interference. Nor would it be in the public interest to force FDA

[1] Plaintiff Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan, Inc., which also holds 97% ownership and control of plaintiff Matrix Laboratories. *See* Mylan Inc. Form 10-K (filed Feb. 24, 2011) at 3-4, *available at* http://investor.mylan.com/secfiling.cfm?filingID=950123-11-17896.

to make an early decision about exclusivity when scientific issues – which may affect that decision or make its timing much less urgent than Mylan alleges – remain to be resolved.

Accordingly, for the reasons set forth more fully below, this Court should deny Mylan's motion for preliminary injunction and dismiss its complaint for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

STATUTORY AND REGULATORY BACKGROUND

A. New Drug Applications

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), pharmaceutical companies seeking to market the initial version of a drug (also known as the "innovator" or "pioneer" drug) must first obtain FDA approval by filing a new drug application ("NDA") containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. § 355(a), (b). An NDA applicant must also submit information on any patent that claims the drug, or a method of using the drug, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1), (c)(2). FDA publishes the patent information it receives in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), *available at* http://www.fda.gov/cder/ob/. *See also* 21 C.F.R. § 314.53(e).

B. Abbreviated New Drug Applications

The Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282, permits the submission of abbreviated new drug applications ("ANDAs") for approval of generic versions of approved drug products. 21 U.S.C. § 355(j). ANDA applicants need not submit clinical data to demonstrate the safety and efficacy of their product, as in an NDA.

Rather, an ANDA relies on FDA's previous findings that the product approved under the NDA is safe and effective. Specifically, under 21 U.S.C. § 355(j), the agency approves duplicates of "listed" drugs[2] on the basis of chemistry, manufacturing, and bioequivalence data without evidence from literature or clinical data to establish effectiveness and safety. Under these provisions, if an ANDA applicant establishes that its proposed drug product has the same active ingredient, strength, dosage form, route of administration, labeling, and conditions of use as a listed drug, and that it is bioequivalent[3] to that drug, the applicant can rely on the fact that FDA has previously found the listed drug to be safe and effective.

1. Patent Certifications

The Hatch-Waxman Amendments were intended to balance encouraging innovation in drug development with accelerating the availability of lower cost alternatives to innovator drugs. *See* H.R. REP. NO. 98-857 (Part I), 98th Cong., 2d Sess. at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48. The timing of approval of ANDAs depends, in part, on patent protections for the pioneer drug.

Among other things, an ANDA must contain one of four specified certifications for each patent that "claims the listed drug" or "a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii). This certification must state one of the following:

(I) that the required patent information relating

[2] FDA has defined the "listed drug" to mean the approved new "drug product." 21 C.F.R. § 314.3(b).

[3] Two drugs are considered bioequivalent if, in general, the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug. 21 U.S.C. § 355(j)(8)(B).

> to such patent has not been filed;
> (II) that such patent has expired;
> (III) that such patent will expire on a particular date; or
> (IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

See 21 U.S.C. § 355(j)(2)(A)(vii). If an applicant wishes to challenge the validity of a patent, or to claim that the patent would not be infringed by the product proposed in the ANDA, the applicant must submit a "paragraph IV certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[4] The applicant must also provide notice of its paragraph IV certification to the NDA holder and the patent owner explaining the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B).

The filing of a paragraph IV certification "for a drug claimed in a patent or the use of which is claimed in a patent" is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This enables the NDA holder and patent owner to sue the ANDA applicant. If such a suit is brought within 45 days of the date notice of the certification was received by the patent owner or NDA holder, FDA must stay approval of the ANDA for 30 months from that date (commonly referred to as the "30-month stay"), unless a final court decision is reached earlier in the patent case or the court orders a longer or shorter period. 21 U.S.C. § 355(j)(5)(B)(iii). If no action is brought within the requisite 45-day period, FDA may approve an ANDA with a paragraph IV certification effective immediately, provided that other conditions for approval have been met. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

[4] If a certification is made under paragraph I or II of 21 U.S.C. § 355(j)(2)(A)(vii) indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired, the ANDA may be approved immediately. 21 U.S.C. § 355(j)(5)(B)(I). A paragraph III certification indicates that the ANDA applicant does not intend to market the drug until after the applicable patent has expired, and approval of the ANDA may be made effective on the expiration date. 21 U.S.C. § 355(j)(5)(B)(ii).

2. 180-Day Period of Market Exclusivity

The statute provides an incentive and reward to generic drug manufacturers that expose themselves to the risk of patent litigation. The applicable older version of the statute does so by granting, in certain circumstances, a 180-day period of marketing exclusivity *vis-à-vis* other ANDA applicants to the manufacturer who is first to file an ANDA containing a paragraph IV certification to each listed patent, as follows:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing][5] such a certification, the application shall be made effective not earlier than one hundred and eighty days after-
>
> > (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
> >
> > (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2002);[6] *see Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 52-53 (D.C. Cir. 2005); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

Thus, under the FDCA, an ANDA applicant with a paragraph IV patent certification that is

---

[5] Courts have observed that the word "continuing" as it appears in the statute reflects a typographical error and should probably be read as "containing." *See Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1203 n. 3 (D.C. Cir. 1998); *Mova*, 140 F.3d at 1064 n.3. *See also* 21 C.F.R. §§ 314.107(c)(1) & (2).

[6] Congress amended 21 U.S.C. § 355(j) in 2003. *See* The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the "MMA"). The relevant provisions of these amendments do not apply to the patent certifications at issue in this case because the first relevant certification was submitted before the December 8, 2003 enactment date of the amendments. *See id.* § 1102(b)(1).

"previous" to all others for that patent will be eligible for a 180-day exclusivity period. During that period, it can market its product, and approvals of other ANDAs for the same product are not permitted. This 180-day exclusivity is triggered by the earlier of (i) the ANDA applicant's first commercial marketing of the drug (the "commercial-marketing trigger"), or (ii) a decision of a court finding the patent at issue invalid or not infringed (the "court-decision trigger"). *Id.* at 1064-65.

Under this version of the statute, no other event triggers exclusivity or otherwise affects the running of the exclusivity period. By contrast, under the 2003 MMA Amendments, there is no "court decision trigger," but the statute provides for the forfeiture of exclusivity under specified circumstances. *See* 21 U.S.C. § 355(j)(5)(D) (2011).

3. Tentative and Final ANDA Approval

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. *See* 21 C.F.R. § 314.105(d); *see generally Barr Labs. v. Thompson*, 238 F. Supp. 2d 236, 245-50 (D.D.C. 2002).[7] An application with a tentative approval has a delayed effective date, and will not become finally approved until the agency issues a final approval letter. *See* 21 C.F.R. § 314.105(d); 21 C.F.R. § 314.107(b)(3)(v). Mylan has not received a tentative approval of its ANDA.

[7] Congress expressly defined "tentative approval" in the MMA (*see* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA)), but that definition technically does not apply to the applications in this case because the first relevant paragraph IV certification was submitted before the December 8, 2003 enactment date of the amendments. *See* Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) § 1102(b)(1).

4. Denial of ANDA Approval

Congress has listed several situations under which an ANDA cannot be approved. 21 U.S.C. § 355(j)(4); *see also* 21 C.F.R. § 314.127. If FDA determines that an ANDA cannot be approved under one or more of those provisions, FDA may issue a "complete response" letter to the applicant stating that its application is not approvable in its present form for reasons given in 21 C.F.R. § 314.127. *See* 21 C.F.R. § 314.110. The applicant can request a hearing on the question whether there are grounds for denying approval of the ANDA under 21 U.S.C. § 355(j)(4). *See* 21 C.F.R. § 314.110(b)(3). Within 60 days of such a request, the agency will either approve the ANDA or refuse to approve the ANDA under 21 C.F.R. § 314.127, and give the applicant written notice of an opportunity for a hearing under 21 U.S.C. § 355(j)(5)(E) and 21 C.F.R. § 314.200 on the question whether there are grounds for denying approval of the application. *Id.* Hearings on the denial of approval of applications are not public. *See* Final Rule, Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications, 73 Fed. Reg. 39,588, 39,596 (Jul. 10, 2008) ("These hearings are not open public hearings; appearance and participation are governed by [21 C.F.R.] § 12.40 though 12.45.") (citing 21 C.F.R. § 314.201). Ultimately, FDA's decision may be appealed in a judicial action. *See* 21 U.S.C. § 355(h) (providing for review in a court of appeals "from an order of the Secretary refusing or withdrawing approval of an application under this section"); 21 C.F.R. § 10.45 (describing general procedures for judicial review of final agency action).

C. Citizen Petitions To FDA

FDA regulations permit any "interested person" to "petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of

administrative action." 21 C.F.R. § 10.25(a); *see* 21 C.F.R. § 10.30. "In fact, the FDA's regulations under the FDCA *require* that a request that the 'Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act.'" *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21 (D.D.C. 2008) (dismissing plaintiffs' claims for failure to exhaust their administrative remedies, stating that "the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed"; quoting 21 C.F.R. § 10.45(b)) (emphasis in original).

By regulation, FDA must issue at least a tentative response to a citizen petition within 180 days. 21 C.F.R. § 10.30(e)(2). In 2007, Congress enacted 21 U.S.C. § 355(q) to direct FDA to make final decisions on citizen petitions relating to certain drug approvals within 180 days after the petition is submitted. 21 U.S.C. § 355(q)(1)(F). For most such citizen petitions, once 180 days have passed, the statute deems FDA to have taken final agency action for purposes of judicial review. 21 U.S.C. § 355(q)(2)(A). Congress, however, expressly exempted from the scope of the provision "a petition that relates solely to the timing of the approval of an application pursuant to [21 U.S.C. § 355(j)(5)(B)(iv)]." 21 U.S.C. § 355(q)(4)(A). The statute thus assures that FDA (and not applicants) exercises control over the timing of exclusivity and generic drug approval decisions, and that citizen petitions may not force FDA to act prematurely.

FACTUAL BACKGROUND

A. Pfizer's NDA for Lipitor

Pfizer holds NDA No. 20-702 for Lipitor, the brand-name version of atorvastatin calcium, a drug approved as an adjunct therapy to diet, *inter alia*, to reduce the risk of myocardial

infarction (heart attacks), stroke, revascularization procedures, and angina.[8] Currently, five patents are listed in the Orange Book for Lipitor.[9] The pediatric exclusivity for two of those patents will expire on June 28, 2011. *See id.*

Pfizer has announced that it has granted Watson Pharmaceuticals Ltd. the exclusive right to sell an authorized generic version of Lipitor, beginning in November 2011. *See* Pfizer Inc. Form 10-K at 10, *available at* http://www.pfizer.com/files/annualreport/2010/form10k_2010.pdf.

B. Ranbaxy's ANDA for Atorvastatin

Ranbaxy has acknowledged that it has filed an ANDA for atorvastatin. *See* Ranbaxy Mem. in Support of Mot. to Intervene at 1 (filed Mar. 25, 2011). Ranbaxy believes that it was the first applicant to have filed an ANDA with paragraph IV certifications challenging Pfizer's patents – and that it should therefore be eligible for 180-day exclusivity. *Id.* Pfizer sued Ranbaxy for patent infringement; the parties subsequently settled their case and have publicly stated that the settlement agreement allows Ranbaxy to market generic atorvastatin on November 30, 2011.[10]

Ranbaxy's ANDA has not received tentative approval, nor has any other ANDA for

---

[8] *See* approved labeling for Lipitor, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf.

[9] *See* Electronic Orange Book, *available at* http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020702&Product_No=001&table1=OB_Rx.

[10] *See* Ranbaxy and Pfizer settle Lipitor Litigation Worldwide (Jun. 18, 2008), *available at* http://www.ranbaxyusa.com/newsdisp180608.aspx.

atorvastatin.[11]

C. Application Integrity Policy

FDA has instituted a discretionary Application Integrity Policy ("AIP"), which may be invoked when the agency finds evidence of a pattern or practice of wrongful conduct that raises a significant question about the reliability of data.[12] When invoked, FDA may defer scientific review of pending applications that are potentially affected by any of the wrongful acts that raised questions about reliability. *Id.* FDA retains the discretion to review and act on applications in special circumstances. *See* Compl. Ex. C. at 5.

FDA invoked this policy against Ranbaxy on February 25, 2009, for its site located at Paonta Sahib in India. *See id.* FDA is engaged in ongoing and confidential discussions with Ranbaxy to resolve the issues identified in the AIP letter.

D. Plaintiffs' ANDA for Atorvastatin

Matrix acknowledges that it has filed an ANDA for atorvastatin. *See* Compl. ¶ 4. Pfizer sued Mylan and Matrix for infringement of some of its atorvastatin patents in 2009. *Pfizer Inc. v. Mylan Inc.*, No. 09-cv-441 (D. Del. Jun. 15, 2009). The parties announced on January 25, 2011,

---

[11] FDA posts tentative approvals on its website. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu.

[12] *See* Application Integrity Policy Procedures at 10, *available at* http://www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/UCM072631.pdf; *see generally* "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy," 56 Fed. Reg. 46,191, 46,199-46,200 (1991); Application Integrity Policy, *available at* http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm; FDA, Compliance Policy Guide § 120.100 (1991), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073837.

that the litigation had settled, but the terms of the settlement agreement are confidential.[13]

Before settlement, Mylan had attempted to "trigger" 180-day exclusivity by seeking a declaratory judgment that the patents remaining for Lipitor after June 28, 2011, were invalid or not infringed. *See Pfizer Inc. v. Mylan Inc.*, 09-cv-441 (D. Del.), Defendants' Reply In Support of Renewed Motion for Leave to File an Amended Answer, Separate Defenses and Counterclaims, Dkt. No. 177 (filed Nov. 30, 2010) (attached hereto as Exhibit A).[14] If Mylan had succeeded in obtaining such a judgment, any exclusivity for those patents would have been extinguished after 180 days. Rather than pursue that avenue, however, Mylan chose instead to settle with Pfizer and file this lawsuit attempting to force FDA to make the exclusivity decision it seeks.

---

[13] *See* Mylan Announces Lipitor® Settlement Agreement (Jan. 25, 2011), *available at* http://investor.mylan.com/releasedetail.cfm?ReleaseID=545363.

[14] Mylan argued:

> Pfizer erroneously argues that Mylan "seek[s] to destroy Ranbaxy's vested 180-day exclusivity period," as if the controversy between Mylan and Pfizer violates Ranbaxy's right to exclusivity. Pfizer Opp. at 12. To the contrary, under applicable pre-MMA law, Ranbaxy's exclusivity period will properly expire – not be "destroyed" – on the 181st day after a final court decision of noninfringement or invalidity of the '104, '156, and '971 patents. The Federal Circuit's decision in *Teva*, applying the same pre-MMA law that applies here, demonstrates that Mylan's justiciable injury arises directly from Pfizer's listing of the '104 and '971 patents in the Orange Book and subsequent failure to assert them against Mylan upon receiving Mylan's Notice Letter. *Id.* (citing *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1347 (Fed. Cir. 2010)).

Id. at 4 n.3.

ARGUMENT

I. Plaintiffs' Complaint Should Be Dismissed

The federal judicial power is limited by Article III of the Constitution to the resolution of "cases" and "controversies." *See, e.g., Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982). To invoke federal court jurisdiction, a party must establish the existence of a "justiciable controversy" with the adverse party – one that is "definite and concrete, touching the legal relations of parties having adverse legal interests." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). A plaintiff must also establish that its claim is ripe. "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." *Texas v. United States*, 523 U.S. 296, 300 (1998) (citations omitted). The party seeking to invoke the jurisdiction of a federal court bears the burden of establishing that the court has jurisdiction. *U.S. Ecology, Inc. v. U.S. Dep't of Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000).[15]

To state a claim upon which relief may be granted, a plaintiff's allegations must "possess enough heft to 'sho[w] that the pleader is entitled to relief.'" *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1966 (2007) (citations omitted); *see also Aktieselskabet AF 21. November 2001 v. Fame Jeans Inc.*, 525 F.3d 8, 17 n. 4 (D.C. Cir. 2008). The court must treat the complaint's factual allegations as true and draw all reasonable inferences therefrom in the plaintiff's favor, *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003), but the

[15] Claims for declaratory relief may also go forward only if jurisdiction otherwise exists. 28 U.S.C. § 2201 ("In a case of actual controversy within its jurisdiction . . . any court . . . may declare the rights. . . ."); *Public Service Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 242 (1952) (Declaratory Judgment Act "applies . . . only to 'cases and controversies in the constitutional sense.'") (quoting *Aetna Life Ins. Co.*, 300 U.S. at 240); *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-72 (1950)) (the Declaratory Judgment Act provides a discretionary, procedural remedy that courts may award, but it does not confer or expand a court's jurisdiction).

court need not accept as true legal conclusions cast as factual allegations or inferences unsupported by facts set out in the complaint. *Warren v. Dist. of Columbia*, 353 F.3d 36, 40 (D.C. Cir. 2004).

A. Plaintiffs Lack Standing

"Under Article III of the Constitution, federal courts may adjudicate only actual, ongoing cases or controversies. To invoke federal jurisdiction, a litigant must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477 (1990) (citations omitted); *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 129 S. Ct. 1142, 1148 (2009); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Int'l Bhd. of Teamsters v. Transp. Sec. Admin.*, 429 F.3d 1130, 1134 (D.C. Cir. 2005); *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Defenders of Wildlife*, 504 U.S. at 561.

The "actual injury" must be "concrete in both a qualitative and temporal sense." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). The injury must be "distinct and palpable" and "actual or imminent," not "conjectural" or "hypothetical." *Id.* (citations omitted). To establish injury in fact, a "plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action, not that he can imagine circumstances in which he could be affected by the agency's action." *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 688-89 (1973); *see also Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc) (plaintiff must show that a particularized injury is at least imminent). The requirement of injury in fact is not satisfied "simply because a chain of events can be hypothesized in which the action challenged eventually leads to actual injury." *Nw.*

Airlines, Inc. v. FAA, 795 F.2d 195, 201 (D.C. Cir. 1986).

Here, neither of the plaintiffs has alleged an injury sufficiently imminent and concrete to establish Article III standing. Plaintiff Matrix states that it is the sponsor of an ANDA for atorvastatin, and that its application has been pending at FDA for more than two years. Compl. ¶ 4. Plaintiff Mylan states that it intends to distribute atorvastatin tablets manufactured by Matrix upon FDA's approval of that ANDA. *Id.* Mylan states that it "*could* obtain approval of the product as early as June 28, 2011, *upon completion* of FDA's regulatory review process." Compl. ¶ 49 (emphases added). Mylan's ANDA, however, has not received even tentative approval from FDA, indicating that there remain issues concerning whether the application is scientifically approvable in the first instance, irrespective of any exclusivity period to which it might ultimately be subject. 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, and thus lacks standing to pursue its claims in this case.

Nor is it by any means certain that Mylan's ANDA will be tentatively approved by June 28, 2011. For example, Pfizer, the NDA holder, filed a citizen petition in 2005 asserting that ANDA applicants were seeking approval of "amorphous" (*i.e.*, non-crystalline) forms of atorvastatin, and that such forms were less chemically stable and "may exhibit very different behavior than Lipitor." *See* Pfizer Citizen Petition (Ex. A of petition, page 1), Docket No. 2005P-0452 (filed Nov. 9, 2005) (attached hereto as Exhibit B). FDA issued a tentative response to that petition on May 4, 2006, stating, "[w]e have been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." See Letter from Jane A. Axelrad to William J. Curatolo (May 4, 2006) (attached hereto as Exhibit C). FDA is still reviewing the scientific issues in that petition as they may

apply to pending applications. Any number of other not publicly identifiable scientific and technical issues could also potentially stand as a barrier to tentative approval of Mylan's ANDA.[16]

FDA is well aware of Mylan's desire to be among the first applicants to launch a generic version of Lipitor. The agency is currently managing its review of the pending generic applications for atorvastatin so that FDA review of the applications will be completed as promptly as practicable. Nevertheless, Mylan's ANDA has only been pending with FDA for about two years (Compl. ¶ 4), whereas Ranbaxy's has been pending for nearly nine (Compl. ¶ 7 n.2). The two years during which the Mylan ANDA has been pending may simply be an insufficient period of time to resolve the complex scientific issues involved in approval of an ANDA for atorvastatin.[17] Even with FDA's attention to the scientific issues relating to the pending ANDAs, it is by no means certain that Mylan will resolve its pending scientific issues and the ANDA will achieve tentative approval in the near future.

Mylan asserts that it is being harmed because FDA has not made any public decision about exclusivity (*see, e.g.*, Compl. ¶ 14), but that theory of injury necessarily depends on its own ability to have its ANDA approved; 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. Thus,

---

[16] FDA has prepared an internal memorandum summarizing the current status of the agency's review of Matrix's ANDA. *See* Memorandum from Keith O. Webber, Acting Director, Office of Generic Drugs (April 1, 2011) (Exhibit D hereto). FDA intends to submit this memorandum to the Court under seal, and will serve unredacted copies on the parties once they have entered into a protective order or otherwise agreed upon acceptable terms for the protection of the confidential information contained therein.

[17] Moreover, it was not until around the time that Mylan announced its patent settlement with Pfizer on January 25, 2011, that it first expressed an interest in prompt resolution of the atorvastatin exclusivity issue.

Mylan has failed to allege any imminent or concrete injury at all, let alone an injury traceable to FDA. *See O'Shea v. Littleton*, 414 U.S. 488, 494 (1974); *see also Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (requiring a plaintiff to show that "the injury is certainly impending") (citation and quotation marks omitted). Similarly, Mylan's claimed injury would not be redressed by an exclusivity decision as to Ranbaxy's ANDA if its own application cannot be approved, and this Court could waste its time resolving an issue that may never arise. For all of these reasons, Mylan lacks standing to bring its claims.

B. Plaintiffs' Claims are Not Ripe

Even if Mylan had standing to pursue its claims in this case, its request for an exclusivity decision as to Ranbaxy's ANDA before its own ANDA (or any other) is ready for approval is premature, and thus unripe. As the Supreme Court explained in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967), "injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution." The purpose of this doctrine is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 148-49.

The ripeness doctrine is rooted in both Article III limitations on judicial power and prudential reasons for declining to exercise jurisdiction. *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 58 n.18 (1993). There can be "final agency action" for purposes of the APA – *e.g.*, where an agency exercises its discretion to issue a declaratory order in anticipation of a controversy – but such action may nevertheless be unripe for judicial review because a genuine

"case" or "controversy" does not yet exist. Thus, as the Court of Appeals has explained, "[r]ipeness entails a functional, not a formal, inquiry." *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999).

To determine whether an agency decision is ripe for review, courts examine "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.*, 387 U.S. at 149. In evaluating the fitness of an issue for judicial review, courts should consider whether the issue is "purely legal" *and* whether the agency action is final, *id.*, or, on the other hand, whether "the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998). With respect to the hardship factor, there must be a "sufficiently direct and immediate" impact on the plaintiff's "day-to-day business," such that the plaintiff faces the dilemma of either complying with the challenged agency action or risking prosecution for failure to do so. *Abbott Labs.*, 387 U.S. at 152. A court must also consider "whether judicial intervention would inappropriately interfere with further administrative action." *Ohio Forestry Ass'n*, 523 U.S. at 733. Finally, "[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." *Texas*, 523 U.S. at 300 (internal quotation marks omitted).

Mylan's complaint fails to satisfy *any* of the ripeness criteria. First, Mylan's claims are not fit for review for the same reasons it lacks standing – its own application has not even been tentatively approved. In *Pfizer v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999), the D.C. Circuit dismissed as unripe a challenge by Pfizer to approval of a competitor's ANDA, even though FDA had already answered a citizen petition on the disputed issue, and the ANDA had been tentatively approved. Here, there has been no response to the pending citizen petition and no

tentative approval.

Second, the exclusivity issue is not fit for review because there has been no final agency action. In Count Two of its complaint, Mylan asserts that "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." Compl. ¶ 74 (emphasis added). But Mylan cannot manufacture an agency action when none exists to ripen its claim – FDA has not decided the exclusivity issue yet. Thus, it is not "an exclusivity period for the Ranbaxy ANDA" that has thus far prevented FDA from approving the Mylan/Matrix ANDA. Other barriers to approval remain, not the least of which are (1) Mylan has not even sought approval before June 28, 2011 (*see* PI Mem. at 9 n.4 (acknowledging that June 28, 2011 is the date of expiration of pediatric exclusivity periods for certain Lipitor patents, "and thus the earliest possible date for FDA to approve")); and (2) Mylan's ANDA has not yet satisfied the requirements for tentative approval.

Indeed, Mylan's own allegations reveal the speculative and unripe nature of its claim, hinging on the contingency that Ranbaxy's ANDA contains unreliable data. *See*, *e.g.*, Compl. ¶ 74 ("FDA may not approve an ANDA *if* it contains inaccurate or false data"). 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. Mylan's claims thus raise issues that are not "purely legal," and that require FDA's further factual resolution. Mylan's demand that FDA expedite this decision to suit its business needs only highlights the ongoing nature of the agency's administrative process, which has not yet been formalized into a final, "crystallized" determination on the matter. *See*

Fla. Power & Light v. EPA, 145 F.3d 1414, 1421 (D.C. Cir. 1998). Although FDA is currently engaged in resolving these issues, it does not expect to render a *final* exclusivity decision until an ANDA is otherwise ready to be approved which, as noted, may or may not be before June 28.[18]

Because FDA's exclusivity determination for atorvastatin poses a novel legal issue relating to a complex and large set of facts, this case is readily distinguishable from *Teva v. Sebelius*, 595 F.3d 1313 (D.C. Cir. 2010), in which the D.C. Circuit held that a plaintiff's claims about an exclusivity issue were ripe, notwithstanding that the agency had not yet made an exclusivity decision. In *Teva*, the exclusivity decision was a purely legal issue, and the agency had previously interpreted the governing statute two times. 595 F.3d at 1308-09 ("[The issues] turn on questions of statutory construction . . . and the interpretations chosen by the FDA and proposed by Teva both constitute bright-line rules, impervious, so far as appears, to factual variation.") (internal citations omitted). The court thus determined that the agency had effectively announced its policy, and that "an about-face seems extraordinarily unlikely." *Id.* at 1309. By contrast, FDA has never applied its Application Integrity Policy to deprive an ANDA

[18] *If* Mylan's application *were* to be tentatively approved by June 28, 2011, and *if* FDA were to determine that Ranbaxy *is* eligible for exclusivity, then after June 28, 2011, FDA's exclusivity decision would be the only barrier to approval of Mylan's ANDA. In such event, FDA's exclusivity decision would be final. But even if FDA were to reach a tentative, internal decision before June 28, other intervening events between the date of FDA's initial decision and the date that an ANDA is ready for final approval could cause that decision to change. For example, FDA could uncover additional information in the course of its review that would render Ranbaxy's ANDA not approvable and potentially ineligible for exclusivity under the theory Mylan describes. For these reasons, FDA does not expect to reach or announce a "final" agency decision on the exclusivity issue until an ANDA is otherwise ready to be approved.

It bears noting, moreover, that if FDA were to determine that Ranbaxy's ANDA is *not* approvable, Ranbaxy would have an opportunity for a non-public hearing on that question pursuant to 21 C.F.R. § 314.110(b)(3), and could ultimately seek judicial review of the agency's decision. That process could be quite lengthy before it was complete. In contrast to a decision on exclusivity, a decision on approvability *could* be made at any time, but the ultimate result of such a decision might not be known until Ranbaxy had exhausted its appeals.

applicant of eligibility for exclusivity, and such a determination would necessarily raise issues of fact about data reliability that cannot be resolved by straightforward statutory construction. Thus, the *Teva* rationale leads to the opposite conclusion on these facts: Mylan's claims concerning atorvastatin exclusivity are premature and unsuitable for judicial intervention at this juncture.

Further, Mylan erroneously supposes that a decision by FDA to refuse to approve Ranbaxy's ANDA would result in the immediate extinguishment of any exclusivity to which Ranbaxy might otherwise have been entitled. Each of Mylan's arguments in support of its claim that FDA must "make a decision now whether the Ranbaxy ANDA is eligible for 180-day marketing exclusivity" (PI Br. at 19) is predicated on the assumption that FDA could immediately deny approval of Ranbaxy's ANDA or deem it withdrawn. *Id.* at 19-24. But an FDA decision refusing to approve the Ranbaxy ANDA would not necessarily extinguish the possibility of exclusivity until Ranbaxy had exhausted all of its available appeals. *See* 21 C.F.R. § 314.110(b)(3) (providing for a hearing on the question whether there are grounds for denying approval of an ANDA).

Notably, the applicable version of the exclusivity statute does not provide for any express forfeiture of exclusivity, *see* 21 U.S.C. § 355(j)(5)(B)(iv) (2002), in contrast to the current version of the statute, which expressly provides for several possible forfeiture events, *see* 21 U.S.C. § 355(j)(5)(D). Moreover, courts have been reluctant to interpret any version of the statute in a manner to compromise eligibility for exclusivity. *See Teva*, 595 F.3d at 1318 ("We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve."); *Ranbaxy Labs. v. Leavitt*, 469 F.3d 120 (D.C.

Cir. 2006) (holding that ANDA applicant did not lose exclusivity under older version of statute even after patent serving as basis for exclusivity was delisted). Thus, despite Mylan's attempt to frame its claim as an unremarkable requirement that FDA must deny approval to an ANDA containing fraudulent data, the exclusivity issue in this case is far more complex than Mylan suggests – implicating novel regulatory considerations and complex factual determinations – all of which are properly left to FDA's resolution in the first instance.

Nor has Mylan demonstrated that withholding judicial review now will cause a direct and immediate impact on its day-to-day operations. Mylan would naturally prefer to make business decisions with a high degree of certainty. But it is a large, global enterprise and, like any company, it must routinely make significant investment decisions without any guarantee that its assumptions about the business landscape will remain constant. Nothing prevents Mylan from seeking judicial recourse if and when FDA renders a final exclusivity decision that is not to Mylan's liking.[19] But the burden of participating in such a proceeding later than today "[does] not constitute sufficient hardship for the purposes of ripeness." *See Fla. Power & Light*, 145 F.3d at 1421; *see also Ohio Forestry Ass'n*, 523 U.S. at 735; *Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 165 (D.D.C. 2006). Because Mylan's claims are presently unripe, its complaint should be dismissed for lack of subject matter jurisdiction.

C. FDA's Enforcement Discretion Is Not Reviewable

Mylan's complaint is also subject to dismissal because FDA's ultimate determination to take, or not take, action against Ranbaxy's ANDA (and the timing thereof) is firmly committed to the agency's discretion and not subject to judicial review. *See Heckler v. Chaney*, 470 U.S.

[19] That is not to say that jurisdiction would necessarily lie in such an action, particularly if it challenged, as here, FDA's exercise of enforcement discretion.

821, 831 (1985) ("an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion" and therefore is presumptively unreviewable."); *see also* 5 U.S.C. § 701(a) (judicial review provisions of APA do not apply where "agency action is committed to agency discretion by law"). That presumption of unreviewability may be overcome if "the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers," or 'where the agency has conspicuously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." *Baltimore Gas & Elec. Co. v. FERC*, 252 F.3d 456, 460 (D.C. Cir. 2001).

But if "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion . . . . the statute ('law') can be taken to have 'committed' the decisionmaking to the agency's judgment absolutely." *Chaney*, 470 U.S. at 830; *Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1256-57 (D.C. Cir. 2005) (same); *Schering Corp. v. Heckler*, 779 F.2d 683, 684, 686 n. 19 (D.C. Cir. 1985) (noting that "the FDA must decide whether and how to initiate enforcement proceedings"). In such event, there is no review at all, even for abuse of discretion: "[I]f no judicially manageable standards are available for judging how and when an agency should exercise its discretion, then it is impossible to evaluate agency action for abuse of discretion." *Chaney,* 470 U.S. at 830. The non-reviewability of such decisions is not simply a question of deference – it is jurisdictional. *Baltimore Gas,* 252 F.3d at 458.[20]

[20] Courts have applied section 701(a)(2) to a variety of agency decisions. *See, e.g.*, *Lincoln v. Vigil*, 508 U.S. 182, 191-93 (1993) (decision to discontinue allotment of program funds); *Webster v. Doe*, 486 U.S. 592, 599-601 (1988) (decisions regarding employee termination); *ICC v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 280 (1987) (agency refusal to reconsider its decision); *Baltimore Gas and Elec. Co.*, 252 F.3d at 458 (decision to settle enforcement action);

Here, there are no meaningful statutory or policy standards to overcome the presumption of unreviewability of FDA's decisions for Ranbaxy. Mylan seeks 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." Compl. ¶ 79. But FDA's AIP is discretionary and does not require the agency to act at all, much less in any particular way. *See, e.g.*, 56 Fed. Reg. 46,191, 46,192 (Sept. 10, 1991) (attached as Ex. A to PI Mem.) ("The fraud policy does not establish any requirement that is binding upon any applicant or upon the agency . . . nor does it provide any interpretation or establish any standard by which FDA will determine whether an applicant's behavior is illegal or whether an application contains invalid data or is otherwise legally deficient."). Rather, invoking the AIP only begins a back-and-forth process between FDA and the sponsor to review the underlying data and evaluate their integrity.

Nor does the AIP provide an independent basis to deny exclusivity to Ranbaxy, as Mylan suggests. When promulgating this policy, FDA explained:

> The fraud policy does not establish or impose any new sanctions for wrongful acts. The stated, general objective of the fraud policy, to refuse to approve, or to proceed to withdraw approval of, application[s] containing fraudulent data, is an exercise of agency discretion under the existing statutes and regulations.

Id. at 46,193.

The AIP also requires no timetable for action. FDA specifically rejected a comment requesting a timetable for FDA to reinspect, stating that "FDA believes that it is impractical to incorporate into the fraud policy a timetable for FDA reinspection. FDA inspections will be

---

Nat'l Fed'n of Fed. Employees, 905 F.2d 400, 405-06 (D.C. Cir. 1990) (decision to close military bases); *Coker v. Sullivan*, 902 F.2d 84, 88-89 (D.C. Cir. 1990) (monitoring and taking enforcement action against state programs); *Dina v. Attorney Gen.*, 793 F.2d 473, 475 (2d Cir. 1986) (decision regarding waiver of residency requirement related to immigration status).

scheduled as appropriate in each case based on consideration of a variety of factors, including FDA's review and inspection priorities and the applicant's responsiveness in providing FDA with information . . . ." *Id.* at 46,198-99.

FDA's assessment of the reliability of Ranbaxy's data – and the timing of that assessment – have all the hallmarks of unreviewability, and will "involve a complex balancing of an agency's priorities, [and be] informed by judgments 'peculiarly within its expertise.'" *Schering*, 779 F.2d at 685 (quoting *Chaney*, 470 U.S. at 831). Mylan's request that such a decision be expedited and be made public so that Mylan has access to it would open the door to similar challenges anytime a manufacturer is suspicious that data in a competitor's application may be unreliable. That is a door that has never been opened before, and should not be opened for the first time by this Court.

And with good reason. Only FDA – not Mylan or any other ANDA sponsor – has the authority to enforce the FDCA, and decisions about when and whether to invoke that authority are properly committed to its sole discretion. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). FDA must consider a wide range of factors when it makes enforcement decisions, including the public health, whereas plaintiffs typically pursue narrower interests. Curious third parties have no right to determine when such decisionmaking should occur to facilitate their business planning.

FDA and Ranbaxy are engaged in ongoing and confidential discussions to resolve the issues described in the letter invoking the AIP. If Mylan were to succeed in wresting a premature decision from the agency on the discrete issue raised in this case, it would seriously undermine FDA's enforcement authority by interfering with these larger discussions. Because FDA's exercise of enforcement discretion is not subject to judicial review, Mylan's effort to compel

immediate FDA action with respect to Ranbaxy's ANDA should be rejected, and Mylan's complaint dismissed.

D. Plaintiffs Fail to State a Claim for Unreasonable Delay Under The APA

In addition to the jurisdictional defects outlined above, Mylan's complaint is also deficient because it fails to state a claim for relief under the APA. Mylan argues that FDA has unreasonably delayed or unlawfully withheld action as to whether Ranbaxy is eligible for exclusivity. *See* Compl. ¶ 68 (citing 5 U.S.C. §§ 706 and 701(b)(2)).[21] But "a claim under § 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." *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (emphasis in original). Limiting such claims to *required* agency action "rules out judicial direction of even discrete agency action that is not demanded by law." *Id.* at 65; *see also In re American Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004) ("In considering a charge of unreasonable delay, however, we must satisfy ourselves that the agency has a duty to act. . . ."); *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000) (court intervention appropriate under § 706(1) only where there are "*transparent* violations of a *clear duty* to act") (emphases added). As noted, there is no requirement that FDA make its exclusivity decision before an ANDA is ready for approval, nor does Mylan point to any such requirement.

Indeed, this court recently rejected a similar attempt to compel an early exclusivity decision in *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008). Notwithstanding the plaintiff's claim that FDA's failure to act perpetuated "unnecessary uncertainty," *id.* at 10, the court declined to enter preliminary injunctive relief "because there has been no final agency

[21] 5 U.S.C. § 701(b)(2) defines the term "agency action" but does not provide an independent basis for judicial review of such action apart from, *e.g.,* 5 U.S.C. § 706.

action here as required by Section 704 of the APA, nor has there been a failure to act by the FDA that corresponds to a required duty that has been 'unlawfully withheld or unreasonably delayed' under Section 706(1) of the APA." *Id.* at 8; *see also Biovail*, 448 F. Supp. at 161 (denying motion to force FDA to decide a citizen petition before approving an ANDA, stating, "[t]he court's authority to act under the APA is limited to compelling the agency 'to take a discrete agency action that it is required to take.'"). So too here: FDA has not delayed taking any discrete action it is legally required to take.

Mylan tries in vain to locate a duty to decide the exclusivity question early. First, Mylan cites FDA's statutory obligation to deny approval to an ANDA if it, *e.g.*, does not have adequate manufacturing controls, contains an untrue statement of fact, or does not meet any other requirements for approval. PI Br. at 19-20 (citing 21 U.S.C. § 355(j)(4)). Nowhere in that statute is a requirement that FDA must make an AIP determination, much less at a particular time, and in a public announcement. Moreover, as Mylan itself acknowledges, FDA is precluded by law from disclosing such sensitive information about pending applications. *See* PI Br. at 5 n.1; *see also* 21 C.F.R. § 314.430.

Second, Mylan argues that FDA is required to take action under the AIP if Ranbaxy's atorvastatin ANDA is subject to FDA's February 2009 letter about the Paonta Sahib site. PI Br. at 20-23. Mylan argues that "[i]n light of [FDA's history with the AIP], it 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." *Id.* at 23 (emphases added). Mylan could not be more wrong. It would in fact be "impermissible" for FDA to do the very thing Mylan demands: disclose confidential information related to a pending ANDA. 21 C.F.R. § 314.430. Moreover, the AIP is a wholly discretionary policy and can only be invoked by FDA on its own

timetable, not by interested competitors such as Mylan. *Cf. Buckman*, 531 U.S. at 349 n.4. The AIP furnishes no statutory timeline, much less a deadline, for FDA to act in the manner Mylan demands.

Third, Mylan argues that FDA's regulations require it to deem Ranbaxy's application withdrawn *if* it is covered by the AIP. PI Br. at 23 (citing 21 C.F.R. § 314.110(c)(1)) (emphasis added). Mylan concedes that this regulation only applies if the ANDA has received a "complete response letter," which it does not believe has occurred here, but nonetheless urges FDA to assert its authority under this regulation. *Id*. Mylan itself thus acknowledges that it would be premature to apply this regulation to Ranbaxy's ANDA, and identifies no provision within the regulation that would require FDA to take action at this time.

Fourth, Mylan argues that "FDA possesses inherent authority to make decisions concerning the status of the Ranbaxy ANDA, especially where the *rights* of Plaintiffs and the public are so deeply affected by FDA's refusal to make a decision." *Id.* at 23 (emphasis added). FDA certainly agrees that it possesses authority to make decisions about pending applications, but does not agree that Mylan has a "right" to compel FDA to exercise that authority upon demand. Nor does Mylan have any "right" to the information it seeks about a competitor's pending ANDA.

1. FDA Has Not Unreasonably Delayed Taking Action

Even if this Court could adjudicate Mylan's claim that FDA's failure to issue an immediate public exclusivity decision violates the APA, FDA's asserted "delay" in issuing an exclusivity decision has been anything but unreasonable. The central question in evaluating a claim of unreasonable delay is "whether the agency's delay is so egregious as to warrant mandamus." *Telecomm. Research & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 79 (D.C. Cir.

1984). In *TRAC*, the D.C. Circuit described six factors relevant to that inquiry: (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety in order to hold that agency action is "unreasonably delayed." *Id.* at 80; *see also In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 549 (D.C. Cir. 1999) (quoting *TRAC*, 750 F.2d at 80)).

Those factors do not suggest that FDA has unreasonably delayed in this case. The statute provides no "timetable" for FDA's exclusivity decisionmaking and, as Mylan acknowledges, the primary factors motivating its lawsuit are economic – to facilitate its business planning and to enhance its bottom line. FDA generally makes exclusivity decisions at the time that an applicant is ready for final approval so as to ensure that the decision takes all appropriate facts into account and avoids unnecessary adjudication of issues that are not yet ripe. FDA, and not the plaintiffs or the judiciary, is in the best position to evaluate and arrange its priorities, and its long-standing practice fully satisfies a "rule of reason" here. *See Chaney*, 470 U.S. at 831 ("The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.").

Indeed, Congress itself has recognized that sponsors should not be able to control the timing of FDA's decisions regarding ANDA approvals. When it enacted a requirement that FDA

respond to citizen petitions within 180 days (or else be deemed to have responded), Congress expressly exempted "a petition that relates solely to the timing of the approval of an application pursuant to [21 U.S.C. § 355(j)(5)(B)(iv)]." 21 U.S.C. § 355(q)(4)(A). Given that latitude, and the factually intensive circumstances in this case, it would make no legal or practical sense to force FDA to make a premature decision that would be subject to change.

Resolving the exclusivity issue in this case will not be straightforward. It will require consideration of the governing exclusivity statute and regulations, as well as the Application Integrity Policy and factual determinations about data reliability. It is also quite possible that intervening events could occur that would affect that decision, or that FDA would obtain additional information relevant to that decision. Because the existence and contents of a pending ANDA are confidential, FDA cannot disclose the status of FDA's current decisionmaking process with respect to Ranbaxy's application. Regardless, none of the pending atorvastatin ANDAs are even tentatively approved as of this date (including Mylan's), indicating that each application has one or more unresolved scientific or technical issues. Requiring FDA to make an early exclusivity decision would serve little purpose if no ANDA is approvable within the urgent timeframe that Mylan demands.

The process of resolving the exclusivity issue is well underway and FDA fully intends to reach a decision as soon as practicable. Nor does FDA anticipate that any delay in deciding exclusivity will ultimately prejudice the timing of Mylan's approval, notwithstanding any alleged impediment to Mylan's business planning. Although FDA is aware of such concerns, and is devoting extensive resources to the review of atorvastatin ANDAs and related issues, such matters must also be balanced against a great number of other competing public health priorities. "An agency has broad discretion to set its agenda and to first apply its limited resources to the

regulatory tasks it deems most pressing." *Cutler v. Hayes*, 818 F.2d 879, 896 (D.C. Cir. 1987). Neither Mylan nor any other drug manufacturer has standing to dictate what FDA's regulatory and enforcement priorities should be (or their pace), and its request for judicial intervention in the case of atorvastatin should therefore be rejected.

Because FDA has not unreasonably delayed taking any discrete action it is legally required to take, Mylan's claim of unreasonable delay fails as a matter of law. For this reason, and those set forth above, Mylan's complaint should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

II. Plaintiffs' Motion for a Preliminary Injunction Should Be Denied

Preliminary injunctive relief is an "extraordinary and drastic" remedy that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. NRDC, Inc.*, 555 U.S. 7, 129 S. Ct. 365, 375-76 (2008); *Munaf v. Geren*, 553 U.S. 674, 128 S. Ct. 2207, 2219 (2008); *see also Mpoy v. Fenty*, 674 F. Supp. 2d 163, 165 (D.D.C. 2009) ("Injunctive relief is an extraordinary remedy, and plaintiff bears a substantial burden to obtain it."). To obtain a preliminary injunction, a party must establish that: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction would serve the public interest. *Winter*, 129 S. Ct. at 374.

It is "particularly important" for a movant to demonstrate likely success on the merits. *Astellas Pharma U.S., Inc. v. FDA*, 642 F. Supp. 2d, 10, 16 (D.D.C. 2009) ("[A]bsent a 'substantial indication' of likely success on the merits, 'there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review.'"). Moreover, a party seeking preliminary injunctive relief must demonstrate an actual "likelihood" of success

on the merits, not merely the existence of "questions 'so serious, substantial, difficult and doubtful, as to make them fair ground for litigation . . . .'" *Munaf*, 128 S. Ct. at 2219 (citations omitted). Nor is a mere "possibility" of irreparable harm sufficient to justify such relief:

> Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction. . . . Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.

Winter, 129 S. Ct. at 375-76 (citations omitted, emphasis in original).

A. Plaintiffs Are Not Likely To Succeed On The Merits

Mylan has no likelihood of success on the merits because, as demonstrated above, its complaint is subject to dismissal in its entirety due to lack of jurisdiction and failure to state a claim upon which relief can be granted. Mylan seeks a preliminary injunction "enjoining FDA from continuing to deviate from the law and established Agency policy, and to require FDA to decide now whether Ranbaxy's ANDA is eligible for 180-day marketing exclusivity for its generic atorvastatin ANDA." PI Br. at 32; *see also* (Proposed) Order at 2.[22] But for all of the reasons described above, FDA need not and should not make any such final decision until an ANDA is otherwise ready for approval but for the 180-day exclusivity. The earliest possible date that would occur is June 28, 2011. The *possibilities* that Mylan's ANDA will be scientifically and technically eligible for approval by then and that FDA *may* decide that Ranbaxy is eligible

[22] This request for relief corresponds to Mylan's unreasonable delay claim in Count One of its Complaint. *See* Compl. ¶¶ 67-72. Mylan does not seek a preliminary injunction related to Count Two (Compl. ¶¶ 73-79), which asserts that FDA's "decision" not to approve Matrix's ANDA on the basis of Ranbaxy's exclusivity period is arbitrary and capricious. Presumably Mylan recognizes that it cannot succeed on the merits of bringing such a claim because FDA has not made any such determination. Count Two may be dismissed for all the reasons set forth in Sections IA, IB, and IC *supra*.

for exclusivity that would block approval of Mylan's otherwise eligible ANDA are "future contingent event[s]" that present no hardship to Mylan now and are not fit for review. *Pfizer v. Shalala*, 182 F.3d at 980 (citing *Texas*, 523 U.S. at 300). There is therefore no live case or controversy over that matter at this time. *See Abbott Labs.*, 387 U.S. at 148-49.

To the extent this Court were to consider the "merits" of Mylan's unreasonable delay claim apart from the threshold jurisdictional issues, the sole question for purposes of Mylan's pending motion is whether FDA has violated a non-discretionary obligation to reach a decision on the exclusivity question to facilitate Mylan's business plans, and whether Mylan is entitled to an injunction from this Court to compel such a decision. *See Hi-Tech*, 587 F. Supp. 2d at 8 (construing "likelihood of success" in terms of whether plaintiff had pled a valid APA claim: "Hi-Tech cannot at this time demonstrate a substantial likelihood of success on the merits since its claim is not yet susceptible to judicial review."); *see also Biovail*, 448 F. Supp. at 160 (denying drugmaker's request for a temporary restraining order against FDA because FDA was complying with applicable regulation and no law required agency to act as plaintiff wished).

For all of the reasons previously stated, Mylan has failed to plead a valid APA claim against FDA for unreasonable delay, nor has there been any unreasonable delay. Because Mylan cannot establish any likelihood of eventual success on the merits of its claims, this Court should deny Mylan's request for extraordinary, emergency relief. *See Munaf*, 128 S. Ct. at 2219.

B. Plaintiffs Have Not Established That They Will Suffer Irreparable Harm In the Absence of Preliminary Injunctive Relief

Mylan has also failed to demonstrate that it will suffer irreparable harm absent injunctive relief or that the balance of hardships tips in its favor. Courts insist that only *irreparable* harm that is *likely* justifies the issuance of a preliminary injunction. *Winter*, 129 S. Ct. at 376. Indeed,

"if a party fails to make a sufficient showing of irreparable injury, the court may deny the motion for injunctive relief without considering the other factors." *Astellas*, 642 F. Supp. 2d at 16.[23] Irreparable injury is a "very high standard." *Ark. Dairy Coop., Inc. v. USDA*, 576 F. Supp. 2d 147, 160 (D.D.C. 2008); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 220 (D.D.C. 1996). The injury alleged must be certain, great, actual, and imminent, *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985), and it must be "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981).

In this circuit, mere economic loss – even irrecoverable economic loss, such as Mylan alleges here – does not constitute irreparable harm unless the financial injury is so great as to threaten the continued existence of the movant's business:

> To satisfy the standard of irreparable injury to justify a preliminary injunction, the movants' loss must be "more than simply irretrievable." *Mylan Labs., Inc. v. Thompson*, 139 F. Supp. 2d 1, 27 (D.D.C. 2001); *see also Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). Instead, the injury must be such that it "cause[s] extreme hardship to the business, or even threaten[s] destruction of the business." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1025 (D.D.C. 1981); *see also, Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26 (D.D.C. 2006) (noting that "[t]o successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence.").

Mylan Laboratories, Inc. v. Leavitt, 484 F. Supp. 2d 109, 123 (D.D.C. 2007). *See also Sterling Commercial Credit - Mich. LLC v. Phoenix Indus. I, LLC*, No. 10-2332, 2011 WL 263674 (D.D.C. Jan. 28, 2011) at *7 ("Even unrecoverable losses, however, must have a "serious" effect

[23] As Judge Kavanaugh recently pointed out, "the *Winter* Court rejected the idea that a strong likelihood of success could make up for showing only a possibility (rather than a likelihood) of irreparable harm. In other words, the Court ruled that the movant always must show a likelihood of irreparable harm." *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., joined by Henderson, J., concurring)

on a plaintiff in order to be considered irreparable for purposes of a preliminary injunction.")*;* *Astellas*, 642 F. Supp. 2d at 22 ("it is well-settled that economic loss alone will rarely constitute irreparable harm"); *Hi-Tech*, 587 F. Supp. 2d at 11 ("In this jurisdiction, harm that is 'merely economic' in character is not sufficiently grave under this standard."); *Coal. for Common Sense in Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168-69 (D.D.C. 2008) (finding that "degree of harm" asserted by coalition of pharmaceutical manufacturers did not approach "the level required in this case (*i.e.* so severe as to cause extreme hardship to the business or threaten the very existence of Coalition members")); *Apotex v. FDA*, No. 06-0627, 2006 WL 1030151 (D.D.C. Apr. 19, 2006) at * 17 (where plaintiff did not establish that lost sales and market share would cause "extreme hardship" to company, claim of harm fell "well short of the serious, irretrievable damage to its business required to warrant a preliminary injunction"); *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001) ("financial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business").

Thus, in order to prevail on its motion for preliminary injunctive relief, Mylan must make "a strong showing" that any economic loss it would suffer in the absence of preliminary injunctive relief "would significantly damage its business above and beyond a simple diminution in profits." *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 43 (D.D.C. 2000); *see also Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 n. 3 (D.C. Cir. 1977) ("The mere existence of competition is not irreparable harm, in the absence of substantiation of severe economic impact."). Mylan does not come close to satisfying this standard.

Mylan contends that "FDA's failure to disclose to Plaintiffs information that is critical to Plaintiffs' ability to launch a generic version of LIPITOR® is causing Plaintiffs irreparable

harm." Br. 15. Specifically, Mylan asserts that it "need[s] to know immediately whether the Ranbaxy ANDA will be denied 180-day marketing exclusivity" in order to plan for the launch of its own generic atorvastatin product. *Id.* at 16. According to Mylan, it faces the dilemma of either (a) preparing for a June 2011 launch (on the assumption that Ranbaxy will be denied exclusivity), thereby risking the loss of millions of doses of expired product and associated capital expenditures if Ranbaxy is granted exclusivity and Mylan's launch is delayed to November 2012 or beyond; or (b) delaying its preparations for launch (on the assumption that Ranbaxy will be granted exclusivity), thereby risking the loss of market share if it turns out that Ranbaxy is denied exclusivity and generic marketing commences in June 2011. "In either case," according to Mylan, "FDA's silence denies Plaintiffs the ability to make rational business plans, and forces Plaintiffs to choose between which harm they are less willing to risk." Br. 29.

In short, Mylan's alleged harm boils down to a claim that FDA's decisionmaking process for Ranbaxy's ANDA impairs Mylan's business decisionmaking for its own ANDA. But even if FDA had already reached a decision on Ranbaxy's ANDA and publicly announced it, Mylan still would not know with certainty when it could launch its product because its own ANDA is not yet ready for approval. At this moment, it is utterly conjectural when or, indeed, whether Mylan will gain approval to market its own generic version of Lipitor. Thus its claimed harm would not be redressed by the preliminary relief it seeks in any event. Unless and until Mylan's own ANDA is at least tentatively approved, the status of Ranbaxy's ANDA is irrelevant.

Moreover, even if Mylan's ANDA were ready for approval, the "harm" it is allegedly suffering due to the uncertainty surrounding its putative launch date does not constitute "irreparable" harm sufficient to justify the extraordinary remedy of a preliminary injunction. That Mylan must make investment decisions in an uncertain business climate is hardly novel in

the drug industry – or any other industry – and is a far cry from the type of harm at issue in *Mova Pharmaceutical Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), on which Mylan relies. According to Mylan, *Mova* stands for the proposition that "being falsely denied the right to be the earliest generic manufacturer constitutes irreparable harm." Br. 26. But, unlike the plaintiff in *Mova*, Mylan has not been stripped of 180-day exclusivity or any "right" to market atorvastatin before its other competitors. The only thing Mylan has been denied is access to information to which it has no entitlement in the first place. The resulting uncertainty of which it complains is far different from the loss of marketing exclusivity at issue in *Mova*.

Not only is confidentiality required by statute and regulation (*see* 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 21 C.F.R. § 314.430, 21 C.F.R. § 20.61) but it is, and always has been, FDA's unvarying practice to decline comment on pending ANDAs, as Mylan well knows. The restrictions on FDA's ability to divulge confidential information in pending applications have been in place since before the Hatch-Waxman Amendments were enacted in 1984, *see* 21 C.F.R. § 314.14(c) (1983)), and FDA has consistently adhered to them. The agency generally will avoid even confirming the existence of an ANDA unless the ANDA sponsor has already publicly acknowledged its existence. Thus it is no surprise that FDA has remained silent with respect to Ranbaxy's ANDA in this case. What is surprising is that Mylan would even suggest that it should be otherwise – particularly in light of the pains Mylan has taken to secure its own confidential ANDA information in this very case. *See* Motion for Leave to File Documents Under Seal (Dkt. 8).[24]

[24] Although Mylan may not be seeking access to Ranbaxy's trade secrets or other proprietary information, knowledge of an ANDA's approval status alone can be just as critical, as any Wall Street trader would attest. Drug manufacturers and investors alike would surely profit from knowing what companies have submitted ANDAs for any given drug and how close they are to approval. But Mylan is no more entitled to such information about its competitors' applications

In short, the assumptions underlying Mylan's claim for preliminary relief – that (a) FDA must make an immediate decision on Ranbaxy's ANDA, and (b) its decision should be publicly announced – are demonstrably wrong. But even without such information, Mylan is suffering no cognizable harm due to any action or inaction of FDA. This Court cannot be responsible for ameliorating any uncertainty surrounding Mylan's inherently risk-based investment and other business decisions. Such decisions are always subject to uncertainty. But no one (least of all FDA) is preventing Mylan from making business decisions concerning how much atorvastatin to manufacture and when to manufacture it.

Indeed, Mylan has already done so – choosing to hedge its bet by manufacturing only enough atorvastatin to meet a 20% market share, rather than more aggressively seeking to obtain a 40% market share, with a commensurately higher risk of loss in the event it should be unable to begin marketing as early as it desires. *See* Declaration of Anthony Mauro ("Mauro Decl.") ¶ 20; Declaration of Hari Babu ("Babu Decl.") ¶ 14. In other words, despite lacking all of the information it might wish to have, Mylan is preparing for the launch of its generic atorvastatin product in the same way it undoubtedly prepares for any other product launch – by attempting to forecast, on the basis of available information and past experience, the anticipated product demand, the number of potential competitors, the projected launch date, the amount of product necessary to meet demand, and a host of other factors – many of which are unknown, uncertain, contingent, or otherwise subject to change. Nevertheless, businesses can and do act on such information every day. It is therefore not surprising that Mylan fails to cite a single case in which a court has made a finding of irreparable harm in even remotely similar circumstances.

---

than they are to Mylan's. Notwithstanding Mylan's insistence that it has a right and a need to know the current status of Ranbaxy's atorvastatin ANDA, the only ANDA information to which Mylan has any legitimate claim is its own.

Even if the uncertainty of which Mylan complains could be construed as harm, Mylan fails to quantify it in any meaningful way. Mylan's principal claim of harm appears to stem from the above-noted decision to seek only a 20% atorvastatin market share because, had FDA made a "timely" decision on Ranbaxy's exclusivity two months ago, Mylan would assertedly have "geared up for production sufficient to meet a greater share of the generic market" Br. 17-18. Mylan thus blames FDA for its decision to forego seeking a 40% share of the atorvastatin market and an asserted [redacted] in additional revenue during the first year after launch. Babu Decl. ¶ 14; Mauro Decl. ¶ 20.[25] But even accepting the accuracy of Mylan's revenue forecast, there is no assurance that Mylan's investment risk would have paid off. Mylan's assumption that it would have captured 40% of the market had FDA announced a decision in January is pure conjecture – especially in light of Mylan's inability to know whether its own product will obtain final approval in time for a June launch and how many other ANDAs may be approved at the same time.[26]

Mylan's claim of harm is also far too insubstantial to warrant preliminary injunctive relief. As noted above, economic loss such as Mylan alleges here will only be considered

[25] Mylan also points to inventory and capital expenditures of [redacted] that will assertedly be lost if launch is delayed and the previously manufactured product goes unsold. Babu Decl. ¶ 22.

[26] Moreover, any such harm that Mylan may have suffered from its decision to seek a lesser market share has already occurred and would not be redressed by the relief it now seeks. Ordering FDA to announce an immediate decision on Ranbaxy's ANDA would not undo any alleged harm that Mylan may have suffered in the past and would, at most, potentially forestall the unnecessary manufacturing of additional product in the event FDA concludes that Ranbaxy's exclusivity will preclude a June launch for other generics. Should FDA conclude that Ranbaxy does not have exclusivity, Mylan does not suggest that it would attempt to alter its manufacturing plans and produce additional product sufficient to capture a larger market share or that it would even be possible to do so. As such, it is difficult to see what Mylan stands to gain from its request that FDA be preliminarily enjoined to issue an immediate decision as to Ranbaxy's exclusivity.

irreparable if the injury is so great as to "'cause extreme hardship to the business' or threaten its very existence." *Mylan v. Leavitt*, 484 F. Supp. 2d at 123; s*ee also Mylan v. Shalala*, 81 F. Supp. 2d at 42-43 (movant must make "a strong showing" that any economic loss it would suffer in the absence of preliminary injunctive relief "would significantly damage its business above and beyond a simple diminution in profits"). Mylan does not even attempt to make such a showing in this case. Nor could it. Mylan asserts that the additional [redacted] in revenue it purportedly could have generated with an earlier FDA exclusivity decision amounts to roughly [redacted] of its annual U.S. revenue. Mauro Decl. ¶¶ 4, 20. Mylan omits, however, that both it and fellow plaintiff Matrix are subsidiaries of Mylan, Inc., the world's third largest generic and speciality pharmaceutical company, with a global portfolio of more than 1,000 different products in over 150 countries, and worldwide annual revenue in excess of $5.45 billion. *See* Mylan Inc. Form 10-K (filed Feb. 24, 2011) at 3-4, 49, *available at* http://investor.mylan.com/secfiling.cfm?filingID=950123-11-17896.

Even accepting Mylan's claims at face value, the additional [redacted] that Mylan says it could have earned amounts to less than [redacted] of Mylan Inc's total annual revenue. But foregoing a potential opportunity to increase its revenue by [redacted] will certainly not cause Mylan "extreme hardship," much less threaten its existence, and Mylan makes no claim that it does. Nor is Mylan's potential loss of [redacted] in product inventory and capital expenditures of sufficient magnitude to cause irreparable harm to a company of Mylan's size. "Monetary figures are relative, and depend for their ultimate quantum, on a comparison with the overall financial wherewithal of the corporation involved." *Mylan v. Leavitt*, 484 F. Supp.2d at 123. When, as here, a company seeking preliminary injunctive relief does not establish that its alleged losses "would threaten the continued existence of [its] business," it "fail[s] to demonstrate irreparable

injury." *Id*.

For all of these reasons, Mylan cannot meet its burden of establishing that it will suffer irreparable injury in the absence of preliminary injunctive relief.

C. The Balance of Harms and the Public Interest Weigh Against the Entry of Preliminary Injunctive Relief

The balance of harms also weighs against an injunction because Mylan's desire for better marketing information does not outweigh FDA's interest in its exercise of enforcement discretion and the timing of its regulatory decisionmaking without judicial interference. *See, e.g., Cutler*, 818 F.2d at 896 ("An agency has broad discretion to set its agenda and to first apply its limited resources to the regulatory tasks it deems most pressing."). Further, Mylan's wish for public information about the status of Ranbaxy's ANDA would prejudice Ranbaxy's own right to the confidentiality of that information, and FDA's responsibility to maintain such confidentiality. Mylan's marketing anxieties do not translate into "rights" that are prejudiced by any FDA action.

Nor would it be in the public interest to force FDA to make an early decision about exclusivity when scientific issues remain to be resolved that might affect that decision or make its timing much less urgent than Mylan alleges. It is certainly not in the public interest to waste judicial resources adjudicating unripe disputes. Mylan alleges that the public will not timely reap the benefits of generic atorvastatin if FDA delays making a decision, PI Mem. at 31, but Mylan's own willingness to ramp up production of its product – at great risk because its product has not even been tentatively approved – suggests that generic applicants will go to great lengths to make generic atorvastatin available at the appropriate time, and that any delays in market entry due to imperfect business planning information will not be significant.

Regardless how the actual marketing unfolds, FDA is the government agency charged

with implementing the statutory scheme governing exclusivity and ANDA approvals. That scheme provides for confidentiality of information in unapproved ANDAs, which necessarily makes business planning difficult among competitors. FDA's interest in implementing this scheme – not Mylan's commercial interests – coincides with the public interest. *Serono Laboratories, Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (determining that the public interest is "inextricably linked" to Congress's purpose in passing the Hatch-Waxman Amendments).

CONCLUSION

For the foregoing reasons, plaintiffs' complaint should be dismissed with prejudice and its motion for a preliminary injunction should be denied.

Of Counsel:

DAVID J. HOROWITZ
Deputy General Counsel

RALPH S. TYLER
Associate General Counsel,
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

WENDY S. VICENTE
Associate Chief Counsel

U.S. Dept. of Health & Human Services
Office of the General Counsel
White Oak 31 Room 4562
10903 New Hampshire Avenue
Silver Spring, MD 20993
Tel: (301) 796-8605
Fax: (301) 847-8638

Respectfully submitted,

TONY WEST
Assistant Attorney General

EUGENE M. THIROLF
Director
Office of Consumer Litigation

/s/
ANDREW E. CLARK
Senior Litigation Counsel
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Tel: (202) 307-0067
Fax: (202) 514-8742
andrew.clark@usdoj.gov

Dated: April 4, 2011

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the Federal Defendant's Motion to Dismiss, Memorandum in Support of Motion to Dismiss and in Opposition to Plaintiffs' Motion for Preliminary Injunction, and Proposed Order to be served via the District Court's electronic filing (ECF) system upon:

Douglas B. Farquhar
Karla L. Palmer
HYMAN, PHELPS & McNAMARA, P.C.
700 13th Street, NW, Suite 1200
Washington, D.C. 20005
Counsel for Plaintiffs

Carmen Shepard
ZUCKERMAN SPAEDER LLP
1800 M Street, NW, Suite 1000
Washington, DC 20036-5802
Counsel for Intervenor-Defendant

this 4th day of April, 2011.

/s/
Andrew E. Clark