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,	)	**[REDACTED]**
Defendant,	)	
and	)	
RANBAXY LABORATORIES LIMITED,	)	
Intervenor-Defendant.	)	

FEDERAL DEFENDANT'S REPLY MEMORANDUM
IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Plaintiffs Mylan Pharmaceuticals Inc. and Matrix Laboratories Ltd. (collectively, "Mylan"), seeking to improve their business planning for a hoped-for launch of generic Lipitor, ask this Court to compel FDA to decide – now – whether Intervenor-Defendant Ranbaxy Laboratories Ltd.'s application may be eligible for exclusivity. In support of this request for an exclusivity decision, Mylan effectively argues that FDA must take enforcement action against Ranbaxy to deny approval of its ANDA because it might contain unreliable data. But Mylan cannot compel FDA to take enforcement action against Ranbaxy based on its suspicions about its competitor's data. And a decision "now" on any of the bases proffered by Mylan to deny Ranbaxy's ANDA would not result in the immediate exclusivity decision that Mylan seeks.

Mylan cites no statute, regulation, or policy that requires FDA to make an early exclusivity decision in order to facilitate Mylan's business planning, and under settled law the underlying enforcement action Mylan seeks is presumed to be unreviewable by the courts. It has long been FDA's practice to make exclusivity decisions when an ANDA has satisfied all scientific and technical requirements and is otherwise ready for approval, so as to avoid premature adjudication of issues that could be affected by intervening events. Departing from this eminently reasonable practice to accommodate Mylan's narrow economic concerns would be particularly senseless in this case in light of (a) Mylan's failure to obtain tentative approval, (b) [redacted], and, (c) the ongoing negotiations between Ranbaxy and FDA concerning FDA's Application Integrity Policy ("AIP") and other matters. In the meantime, FDA is prohibited by law from disclosing the confidential information that Mylan seeks about its competitor's unapproved application.

Failing to establish any legal duty for FDA to take the action Mylan seeks to compel, Mylan now points to a statute setting forth a 180-day timeframe for FDA to decide to approve or disapprove an abbreviated new drug application ("ANDA"), and argues that the agency has unreasonably delayed over nine years in making such a decision for *Ranbaxy's* ANDA. But Mylan acknowledges that this review period can be extended under FDA regulations, and the law does not allow Mylan to stand in Ranbaxy's shoes to object to any such delay. Ranbaxy itself does not complain of any delay in the review of its ANDA, having reached a settlement agreement with Pfizer under which Ranbaxy may begin marketing its product no sooner than November 30, 2011.

At bottom, Mylan is seeking relief in this case that no court has ever before ordered. In fact, we are aware of only one other instance where a drug company has even sought such exotic relief – and its request was soundly rejected by Judge Bates of this Court. *See Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008). Simply put, Mylan has no standing to seek (nor any right to) information concerning the approval status of another manufacturer's ANDA – much less the right to dictate the timing of FDA's decisionmaking or compel the agency to act before it is ready. To the extent Ranbaxy's exclusivity status may ultimately have some bearing on Mylan's own ANDA approval status (*e.g.*, if FDA determines that Ranbaxy is eligible for exclusivity and that exclusivity period will delay the date on which Mylan's ANDA can be finally approved), Mylan will learn about it from FDA only if and when Mylan's own ANDA is otherwise ready for approval.

Until then, Mylan's claims are, at the least, unripe, and it lacks standing to pursue the unprecedented relief it seeks in this case. Because Mylan's own ANDA is neither ready to be

approved, nor certain to gain approval at any specific time, Mylan is not presently suffering, nor is it threatened with, any hardship or otherwise cognizable injury fairly traceable to any action that FDA has taken or failed to take. Neither has FDA unreasonably delayed taking any action it is required to take, nor breached any duty of timeliness that is owed to Mylan. In these circumstances, and for these reasons among others, Mylan's claims in this case are not justiciable, and should be dismissed.

A. Mylan Lacks Standing

Although Mylan bears the burden to establish standing, it cannot overcome the multiple "coulds" and "ifs" in its complaint. Mylan states that it "*could* obtain approval of [its] product as early as June 28, 2011, *upon completion* of FDA's regulatory review process." Compl. ¶ 49 (emphases added); *id.* ¶ 79 ("Plaintiffs are entitled to 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 . . . .") (emphasis added).[1] But Mylan's desire for approval does not translate into certain approval. Further, neither Mylan's suspicion that Ranbaxy's ANDA may be tainted, nor Mylan's uncertainty whether Ranbaxy may be eligible for exclusivity, is an "injury" that entitles *Mylan* to a decision about its *competitor's* application – much less an expedited decision timed to facilitate Mylan's own business planning and financial bottom line. Mylan's claims rest on contingent events that may never occur at all and are too speculative to confer standing.

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[1] *See also id.* ¶ 13 ("Not only are Plaintiffs directly, and negatively, affected by FDA's inaction and failure to make a decision, but likely so are other atorvastatin ANDA sponsors, who similarly must make decisions, including, but not limited to, the commitment of significant financial and human resources in preparation for product launch *if or when* FDA approves their atorvastatin ANDAs.") (emphasis added); *id.* at ¶ 35 ("*If* the Ranbaxy ANDA does not have 180-day marketing exclusivity, Plaintiffs *could* launch their product on, or shortly after, that date, *following completion of FDA's regulatory review process*.") (emphases added).

Just today, Judge Huvelle dismissed the similarly speculative claims of another drug company whose fears about the possible approval of a competitor's ANDA were deemed insufficient to confer standing. *See Viropharma, Inc. v. Hamburg*, No. 10-1529 (D.D.C. Apr. 15, 2011) (attached hereto as Exhibit A). Viropharma's claims of financial harm rested on two contingencies: (1) that FDA would approve a competitor's ANDA; and (2) that Viropharma would disagree with the basis of FDA's decision for that potential approval. Mem. Op. at 7. As to the first ground, the Court held that Viropharma's concerns about approval of another ANDA were speculative, stating that "The Court cannot assume from the mere fact of FDA acceptance of an ANDA for processing that the FDA will ultimately approve the drug." *Id.* As to the second, the Court again dismissed Viropharma's fears: "Moreover, if and when the FDA ultimately approves an ANDA . . . it cannot be assumed that it will rely upon the challenged interpretation." *Id.*

In this case, Mylan's claims of financial harm are likewise premised on actions it has taken based on the possibility that its ANDA will be approved, and that it will not like the outcome of a future FDA decision that could block its approval for 180 days. Under *Viropharma*, these contingencies are fatal to its standing, and its claims of economic harm are not cognizable for purposes of Article III standing:

> In reality, nearly all of the "harms" complained of . . . represent actions that [plaintiff] *elected* to take in response to its own predictions about what the FDA may do in the future, presumably in order to better position itself should these predictions prove accurate. Perhaps these steps will prove to be wise business decisions. Perhaps they will not. Either way, they are not "harms" that can be said to have been caused by the FDA.

Viropharma, Mem. Op. at 10 (emphasis in original).

Mylan argues that its ANDA "is on a clear and reliable path to approval,"

notwithstanding that it has not received tentative approval and that scientific issues pertaining to its application, [redacted] remain unresolved. Mylan Opp. at 5. [redacted].[2]

Mylan concedes that it has failed to gain tentative approval of its ANDA, and that such a failure may be a relevant factor in determining whether it has standing. Mylan Opp. at 6; *see also Teva Pharms. v. Sebelius*, 595 F.3d 1303, 1319 (D.C. Cir. 2010) (noting that after the intervenor had earned tentative approval of its ANDA, "the obstacle to standing on which the

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[2] [redacted]

Mylan complains that FDA's reference to the citizen petition is an "eleventh-hour, post-litigation attempt to explain away the Agency's inaction." Mylan Opp. at 10-11; *see also* Supp. Decl. of S. Wayne Talton ¶ ¶ 11, 14. [redacted] Moreover, Mylan itself put the status of its ANDA at issue when it brought this case, and cannot now complain that it should have to answer to potential obstacles to approval in this litigation context.

district court relied" was effectively removed). Mylan argues that its lack of a tentative approval should not be fatal to standing (Mylan Opp. at 6), but in support of its argument cites cases in which standing was not challenged on that ground and which do not support Mylan's claims to standing here. Indeed, most of the cases Mylan cites involve situations in which there was no dispute as to the standing of the plaintiff instituting the litigation, notwithstanding the approval status of any intervening ANDA sponsors whose applications were placed at issue as a result of the plaintiff's claims.

In *Pfizer, Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999), for instance, it was the brand company, Pfizer, rather than a competing generic, that brought suit to challenge FDA's potential approval of intervenor Mylan's ANDA, which had not yet received tentative approval. While there was apparently no standing objection raised to Mylan's request to intervene, the fact that Mylan's ANDA was not yet ready for approval was nevertheless highly relevant to the justiciability of Pfizer's claims. Indeed, the D.C. Circuit held that Pfizer's challenge to FDA's potential approval of an ANDA was unripe even after the ANDA was tentatively approved: "Although it is now more likely that the FDA will eventually approve Mylan's drug, the agency's tentative approval causes Pfizer no hardship at present or in the near future, nor does it render Pfizer's challenge fit for review." Thus, *Pfizer* stands for the proposition that even a tentative approval does not make speculative claims, like Mylan's here, justiciable.[3]

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[3] Mylan also cites *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), *aff'd sub nom. Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877 (D.C. Cir. 2004), a case in which Purepac had not received a tentative approval when it brought suit. But FDA had denied Purepac's ANDA because the agency concluded that the ANDA did not contain the proper form of certification, and thus Purepac had standing to challenge a final agency action – FDA's denial of Purepac's ANDA. *Id.* at 192. Here, there is no final agency action, and unlike Purepac (which challenged a decision on its own ANDA), Mylan is challenging a yet-to-be-made decision on another company's ANDA. Mylan also points out that intervenor TorPharm did not have a

Under *Pfizer*, even if Mylan were to obtain tentative approval before June 28, 2011, Mylan would still lack standing to compel FDA to make an exclusivity decision before June 28 because it has not sought, [redacted], approval before that date.[4] *A fortiorari*, if Mylan would have no standing with a tentative approval, Mylan has no standing without one. Clearly, the unresolved issues in Mylan's own ANDA are relevant to whether its claims may proceed in this case: Mylan can suffer no cognizable hardship from the uncertain prospect of another applicant's exclusivity if its own application is not ready for approval and it remains uncertain when, or whether, it may be approvable.[5]

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tentative approval, but in this Circuit, "if one party has standing in an action [as Purepac did], a court need not reach the issue of the standing of other parties when it makes no difference to the merits of the case." *Teva v. Sebelius*, 595 F.3d at 1318 (internal citations omitted). *See also TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69 (D.D.C. 2003), *aff'd*, 354 F.3d 877 (D.C. Cir. 2004) (discussing same approvals at issue in *Purepac*). In *Teva Pharms., USA, Inc. v. FDA*, No. 99-67, U.S. Dist. LEXIS 14575 (D.D.C. Aug. 19, 1999), *aff'd*, 254 F.3d 316 (D.C. Cir. 2000), also cited by Mylan, plaintiff Teva had received a tentative approval (unlike Mylan) and its final approval had been delayed by intervenor TorPharm's exclusivity. *Id.* at *12. Thus, the parties litigated final agency action that directly affected their interests. The fact that TorPharm had not received tentative approval apparently did not elicit a standing objection at the time it sought to intervene and, as noted, the court would not have needed to assess that question in any event.

[4] [redacted]

[5] Mylan argues that FDA *could* decide not to issue a tentative approval "and thereby insulate [itself] from adequate, timely judicial review." Mylan Opp. at 7. Mylan's speculation is unfounded. As noted, FDA grants tentative approval to ANDAs when all scientific and technical requirements for approval have been met, but the applicant cannot be fully approved because it is blocked by one or more patents or exclusivity (including another ANDA applicant's 180-day exclusivity). *See* FDA Mot. to Dismiss at 7-8. If no such patent or exclusivity blocks approval of the ANDA when it is otherwise ready, FDA would grant final approval to the ANDA without first granting tentative approval. FDA issues tentative approvals even when they may subject FDA to litigation. In *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1006 (D.C. Cir. 1999), for example, FDA tentatively approved Teva's ANDA, but informed Teva that a previous applicant's exclusivity barred its final approval. Teva sued FDA on that decision. [redacted]

Mylan cites three additional cases for the proposition that Mylan has standing "to protect [its] rights to launch generic drugs early in the formation of the generic market, and to prevent competitors from receiving unlawful grants of marketing exclusivity." Mylan Opp. at 5-6. None of those cases supports Mylan's standing in this case. The first, *Teva v. Sebelius*, 595 F.3d at 1309-12, held that a plaintiff *with a tentative approval* could challenge what the court believed was an imminent FDA decision to deny its exclusivity. The court held that the challenge was justiciable because FDA was poised to take away the *plaintiff's* exclusivity right and FDA's decision was *virtually certain* based on its decisions in two previous cases. *Id.* at 1309. By contrast, Mylan lacks tentative approval, and Mylan seeks a decision to strip its competitor of exclusivity on a novel legal theory with a much less certain outcome.[6]

In *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 35 (D.D.C. 2000), Mylan obtained tentative approval of its ANDA, but challenged FDA's refusal to grant it final approval, based upon the agency's conclusion that, under its regulations, a competitor's 180-day exclusivity period had not yet been triggered and thus blocked final approval of Mylan's ANDA. Mylan's challenge in that case to an actual, specific decision and regulation blocking its approval was nothing like its effort in this case to compel an early exclusivity decision on a competitor's

[redacted] If Mylan's ANDA were ready for approval on June 28, 2011, FDA would either (1) issue a tentative approval of Mylan's ANDA if Mylan's ANDA were subject to a 180-day exclusivity period; or (2) grant final approval to Mylan's ANDA if it were not subject to such an exclusivity period.

[6] FDA's opening brief further distinguished the *Teva* court's holding of justiciability on the ground that *Teva* concerned a purely legal issue, whereas Mylan seeks to compel adjudication of facts relating to data reliability in its competitor's application. FDA Mot. to Dismiss at 20-21. Mylan does not rebut those arguments.

application.

Finally, in *Teva Pharms. USA, Inc. v. Eisai Co.,* 620 F.3d 1341, 1347 (Fed. Cir. 2010), *petition for cert. filed*, 2011 WL 720842 (U.S. Feb. 25, 2011), the Federal Circuit held that it had jurisdiction to hear a declaratory judgment claim by an ANDA holder (plaintiff) that certain patents were invalid or not infringed. The court held that the NDA holder's patent listing was a sufficient "injury" to establish the ANDA holder's standing to sue, but distinguished 180-day exclusivity periods as follows: "In contrast to the listing of a patent in the Orange Book, a first-filer's exclusivity period in itself does not give rise to an injury-in-fact because the resulting exclusion of other generic drug companies from the market results from the inherent framework and intended workings of the Hatch-Waxman Act." *Id.*[7] Thus, the court expressly found that the possibility that an ANDA applicant would be barred from marketing by a 180-day exclusivity period would not give rise to a justiciable injury.[8] So too here. Even if Mylan's ANDA were otherwise ready for approval, *Teva v. Eisai* would not advance Mylan's standing here, which is based on nothing more than Mylan's fear that it might be barred from marketing by a potential competitor's possible 180-day exclusivity period.

Mylan only speculates that its ANDA *might* be eligible for approval in the near future,

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[7] This distinction between putative injuries based on patent listing and exclusivity is consistent with the Federal Food, Drug and Cosmetic Act ("FDCA"), which expressly provides for a declaratory judgment action related to the former, but does not address the latter. *See* 21 U.S.C. § 355(j)(5)(C)(i).

[8] *Teva v. Eisai* further illustrates that Mylan had available to it a different route to seek the result it desires in this case: elimination of any effective exclusivity for atorvastatin by bringing a declaratory judgment counterclaim for patent invalidity or noninfringement and triggering any such exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002). *See* FDA Mot. to Dismiss at 12 & n.14. Rather than pursue that route, Mylan abandoned its patent claims in its settlement with Pfizer and chose instead to bring this action against FDA.

and that its competitor *might* be eligible for 180-day exclusivity. In these circumstances, Mylan plainly lacks standing to pursue its claims. *See Viropharma*, Mem. Op. at 7-10; *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).

B. Mylan's Claims are Not Ripe

Mylan's claims are also not ripe. First, they are not "fit" for judicial review because Mylan raises intensely factual issues about possible future decisions. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998). Second, Mylan faces no cognizable hardship now stemming from this Court's withholding review because Mylan's alleged "injury" relates to business plans, which are often inherently uncertain. Mylan may attempt to challenge an FDA decision if and when the agency issues a decision not to its liking, but the burden of participating in such a proceeding in the future "[does] not constitute sufficient hardship for the purposes of ripeness." *See Fla. Power & Light v. EPA*, 145 F.3d 1414, 1421 (D.C. Cir. 1998).

Mylan makes no attempt to address these specific requirements for ripeness, but rather refers to its previous arguments citing "numerous cases . . . establishing that ANDA holders are routinely recognized as having standing to *challenge FDA decisions* denying them the ability to launch into a generic market, or denying them marketing exclusivity." Mylan Opp. at 12 (emphasis added). Those cases do not help Mylan. *See* Section A, *supra*. Mylan does not "challenge" an "FDA decision" here – it seeks to compel one, even though it fails to cite a single case in which a court forced FDA to make an early exclusivity decision (much less a decision involving the complex factors at issue here). Mylan's novel claims are premature, and should be dismissed as unripe. *See Texas v. United States*, 523 U.S. 296, 300 (1998) ("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.") (citations omitted).

C. FDA's Enforcement Discretion Is Not Reviewable

Belatedly recognizing that judicial review of FDA's enforcement discretion is foreclosed by *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (see Mylan Opp. at 13), Mylan attempts to jettison the offending portions of its complaint and disavow the very relief it seeks therein. But notwithstanding Mylan's insistence that it is "not seeking an order that FDA enforce the [Application Integrity Policy ("AIP")] against Ranbaxy" (Mylan Opp. at 13), its complaint and initial brief expressly ask for just such relief. *See* Compl. ¶ 79 ("Plaintiffs are entitled to 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 . . . ."); *see also id.* ¶ 68 ("FDA's failure to . . . . state whether FDA will enforce the AIP against the Ranbaxy ANDA, rendering the Ranbaxy ANDA ineligible for 180-day marketing exclusivity, is 'agency action unlawfully withheld or unreasonably delayed'"); Mylan PI Mem. at 4 ("Plaintiffs request that the Court order FDA to promptly issue a decision whether the AIP applies to the Ranbaxy ANDA."); *id.* at 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.").

Now, Mylan says it merely wants the Court "to order FDA to comply with the law" by issuing a "long overdue" exclusivity decision. Mylan Opp. at 13. This wolf in sheep's clothing fares no better than Mylan's first abandoned theory. Each "law" upon which Mylan relies to compel FDA to make this exclusivity decision is predicated on requiring FDA to assess the reliability of data in Ranbaxy's ANDA (if it is subject to the AIP) and to take adverse action on

Ranbaxy's ANDA if those data are unreliable – all on Mylan's preferred timetable.[9] Mylan's request for an exclusivity decision is indistinguishable from a request to take enforcement action against Ranbaxy's ANDA.[10]

Under *Heckler v. Chaney*, 470 U.S. at 832, "an agency's decision not to take enforcement action should be presumed to be immune from judicial review." This presumption can only be overcome "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers. *Id.* at 833. The AIP is a discretionary policy, and does not require FDA to make decisions within a specific timeframe, much less a timeframe to accommodate a competitor's business planning interests.[11]

In a vain, but transparent, effort to overcome the "no law to apply" barrier presented by *Heckler v. Chaney*, Mylan conflates a statutory provision governing the timing for *approval* and *disapproval* of ANDAs with the AIP, a non-binding *policy* that FDA may invoke to defer reviewing applications of a company "when the Agency *suspects* an applicant of committing wrongful acts that raise significant questions about data integrity," until the Agency has resolved

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[9] *See* PI Mem. at 19-24 (arguing that (1) FDA cannot approve Ranbaxy's ANDA if it has unreliable data pursuant to 21 U.S.C. § 355(j)(2)(A); (2) "FDA should deny the Ranbaxy ANDA" under the AIP if it contains unreliable data; (3) Ranbaxy's ANDA should be deemed withdrawn under 21 C.F.R. § 314.110(c)(1) if it is covered by the AIP; and (4) FDA has inherent authority to withdraw approval of an applications tainted by unreliable data).

[10] Nor would any of the cited legal bases to deny approval to Ranbaxy's ANDA necessarily result in an immediate exclusivity decision – because Ranbaxy could and likely would appeal that decision, keeping any exclusivity claim alive until such appeals were exhausted. *See* FDA Mot. to Dismiss at 21. Thus, even if Mylan could compel FDA to take enforcement action in asserted "compliance" with the "laws" upon which Mylan relies – such action would nevertheless fail to provide the fast exclusivity answer that Mylan seeks.

[11] *See* FDA Mot. to Dismiss at 24-25 (citing 56 Fed. Reg. 46,191 (Sept. 10, 1991)).

the issues.[12] *See* Mylan Opp. at 14, 21 (citing 21 U.S.C. § 355(j)(2)(A)). This statute does not provide for the relief Mylan seeks. Whatever 21 U.S.C. § 355(j)(5)(A) says about the timing of approval of ANDAs, it says nothing about a timeline for *exclusivity* decisions, based on the AIP or otherwise. Thus, Mylan has not shown that Congress has limited FDA's exercise of its enforcement power "by setting substantive priorities, or by otherwise circumscribing [FDA's] power to discriminate among issues or cases it will pursue," *see Heckler v. Chaney*, 470 U.S. at 833, and has failed to overcome the presumption that FDA's deferral of the timing of its exclusivity decision until an ANDA is approvable is unreviewable.

D. Mylan Fails to State a Claim for Unreasonable Delay Under The APA

A claim for unreasonable delay "can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required* to take." *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (emphasis in original). Mylan has failed to point to *any* requirement that FDA make an early exclusivity decision, and its claim fails on that basis alone. *See Hi-Tech*, 587 F. Supp. 2d at 8 (denying motion for preliminary injunction to obtain an early exclusivity decision "because there has been no final agency 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") (emphasis added);[13] *see also Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 161

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[12] *See* Application Integrity Policy Procedures at 3, 10 (emphasis added), *available at* http://www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/UCM072631.pdf.

[13] Mylan attempts to distinguish *Hi-Tech* on the ground that Hi-Tech sought to block competitors, but Mylan does not. Mylan Opp. at 22-23. Regardless, both plaintiffs wanted an early exclusivity decision, and Hi-Tech was unable to compel such a decision under its APA theory of unreasonable delay because the court determined that FDA was not required to take any action. *Hi-Tech*, 587 F. Supp. at 9. The same result should apply here.

(D.D.C. 2006) (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*.'") (emphasis added).

Mylan suggests that 21 U.S.C. § 355(j)(5)(A) provides a timeframe for ANDA review within 180 days of submission (Mylan Opp. at 16), and that FDA must decide the exclusivity issue now, "after years of wrongful delay." *Id.* at 20-21. But Mylan misconstrues FDA's decisionmaking under this statute, as well as the content of the resulting decision. By regulation, FDA defines the first 180 days of review after submission as the "initial review cycle." 21 C.F.R. § 314.100(a). This period can be extended by agreement or submission of a major amendment, 21 C.F.R. § 314.100(c), as Mylan is well aware. *See* Mylan Opp. at 14, 16 n.10.[14] The action following the review cycle would be a list of deficiencies or a "complete response letter," not a final up-or-down decision on the application – and certainly not a final exclusivity decision. *See* 21 C.F.R. § 314.110. As described previously, denying approval to an ANDA is a lengthy process, and would only be complete following exhaustion of appeals. Until such time, there would likely be no effective final decision on exclusivity. *See* FDA Mot. to Dismiss at 8, 20-21.

Mylan's claim that FDA has failed to comply with a duty for nine years for Ranbaxy's ANDA is not credible and avails Mylan nothing. The information giving rise to Mylan's suit was not available until February 2009, when FDA invoked the AIP against Ranbaxy's Paonta Sahib site in India. Moreover, Mylan's request to compel FDA to enforce the AIP against

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[14] Mylan also concedes that the median FDA review time for ANDAs is substantially longer than the statutory "goal" of 180 days. *Id.* at 18 n.12 (noting that median time from submission to approval for ANDAs is about 31 months).

Ranbaxy would *defer* review of Ranbaxy's ANDA, not speed it up, as Mylan argues FDA should have done under 21 U.S.C. § 355(j)(5)(A). Mylan can't have it both ways.

Nor does Mylan have standing to compel FDA to apply the timeframe in 21 U.S.C. § 355(j)(5)(A) to another ANDA merely to facilitate its own business planning. *See Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 12 (2004) (stating that "prudential standing encompasses 'the general prohibition on a litigant's raising another person's legal rights'") (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)); *see also Frank Krasner Enters. v. Montgomery County*, 401 F.3d 230, 234-35 (4th Cir. 2005) ("Cases after *Allen* have held that when a plaintiff is not the direct subject of government action, but rather when the 'asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*,' . . . satisfying standing requirements will be 'substantially more difficult.'") (quoting *Allen*, 468 U.S. at 758) (emphasis in original).

Whatever interest Mylan may have in the speedy approval of its own ANDA, it has no interest to assert on behalf of Ranbaxy's or any other competitor's ANDA, and thus no call to complain about any alleged delay. Ranbaxy has not complained that FDA has delayed in approving its application or deciding exclusivity, and has agreed with Pfizer that it will not market a generic atorvastatin product before November 30, 2011. Nor has Mylan complained that FDA has delayed in reviewing its own application, although it has been pending longer than 180 days. Mylan would no doubt cry foul if FDA gave Mylan's ANDA a final up-or-down vote at this time, when scientific issues have not yet been resolved [redacted] [15]

[15] 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

Even if there were a duty to act within the 180-day timeframe Mylan proclaims – which there is not – the timing of FDA's exclusivity decisionmaking easily meets the standards set forth to evaluate unreasonable delay in *Telecomm. Research & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 80 (D.C. Cir. 1984). The first and second *TRAC* factors apply a "rule of reason" to the timing of agency decisions, looking to the statutory scheme for a "timetable" to supply content to that rule. *Id.* The exclusivity statute provides no "timetable" for FDA's exclusivity decisionmaking. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2002). Elsewhere the FDCA firmly places the timing of exclusivity decisions into FDA's hands when sought by a citizen petition. *See* 21 U.S.C. § 355(q)(4)(A); *see also* FDA Mot. to Dismiss at 29-30. FDA's practice of deciding exclusivity when an ANDA is ready to be approved – to avoid its own premature adjudication of that issue, which could be affected by intervening events – fully complies with a "rule of reason." *Cf. Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) ("[T]he formulation of procedures was basically to be left within the discretion of the agencies to which Congress had confided the responsibility for substantive judgments.").

Moreover, FDA is managing its review of the atorvastatin ANDAs so that decisions will be made as promptly as practicable, and at the appropriate time when ANDAs may in fact be ready for approval. If Mylan does obtain tentative approval by June 28, 2011, it will necessarily have an exclusivity decision on that date because it will either be able to market its product, or it

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atorvastatin exclusivity issue. Mylan sued FDA for alleged inaction on atorvastatin exclusivity less than three months after its first letter to FDA on this issue, and without even awaiting a response from FDA. Mylan's newfound urgency is less than compelling considering its belatedness in raising the issue, as well as the fact that its own ANDA is not yet tentatively approved [redacted].

will be blocked by exclusivity. *See* FDA PI Opp. at 20 n.18.[16] Thus, FDA does not contend that "it can take however long it wishes to decide whether Ranbaxy's ANDA will be approved, and therefore whether Ranbaxy is entitled to marketing exclusivity." Mylan Opp. at 13. Rather, FDA will make an exclusivity decision at the time that an ANDA is otherwise ready for approval (but for any exclusivity). FDA's timetable will account for the possibility of Mylan's approvability in the near future, and is eminently reasonable in these circumstances.[17]

The third *TRAC* factor finds delays in the sphere of health and human welfare "less tolerable" than economic delays. *TRAC*, 750 F.2d at 80. Mylan argues that "[p]ublic health and welfare likely are imperiled by FDA's arbitrary failure to make a decision" because FDA's "indecision . . . will keep atorvastatin out of the hands of those who cannot afford brand-name Lipitor." Mylan Opp. at 17-18. FDA is well aware of its mission to protect the public health and is in a far more credible position to protect those interests than Mylan. Notwithstanding Mylan's purported solicitude for public health, Mylan's own claims to harm in this case are purely economic. *See id.* at 18 ("FDA's delay also causes significant and irreparable economic harm to Plaintiffs.").[18]

The fourth factor considers the effect of expediting agency action on higher or competing priorities. *TRAC*, 750 F.2d at 80. FDA, and not the plaintiffs or, respectfully, the judiciary, is in

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[16] [redacted]

[17] Nor should FDA's timetable be stepped up because Mylan has brought this suit. To the contrary, expediting its decisionmaking in such circumstances would set bad precedent, inviting other ANDA sponsors to sue FDA for early decisions upon suspicions about their competitors' applications.

[18] Mylan asserts that its alleged harm "extends beyond economic loss," Mylan Opp. at 23, but each type of harm it claims (losses of market share, goodwill, and access to customers) relates to its own narrow economic interest rather than to any public health concern.

the best position to evaluate and arrange its own priorities. *See Heckler v. Chaney*, 470 U.S. at 831-32 ("The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities."). Mylan claims that it is not asking this Court to force FDA to "expedite" its exclusivity decision, but proffering a "much simpler" request: that "the Court should require FDA to decide now . . . ." Mylan Opp. at 18.[19] But however thinly Mylan slices its argument, a decision "now" would be "expedited" and would interfere with the agency's ordering of its priorities.

This factor alone precluded mandamus relief in *In re Barr Laboratories, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991), in which the D.C. Circuit denied Barr's bid to compel FDA action on numerous pending ANDAs even though FDA had failed to meet the 180-day timeframe in 21 U.S.C. § 355(j)(5)(A) because "we have no basis for reordering agency priorities." The court was concerned that "a judicial order putting Barr at the head of the queue simply moves all others back one space and produces no net gain." *Id.* at 75. So too here. A decision to force an early exclusivity decision would bump other important agency decisions out of their appropriate place in line.

The fifth factor considers "the nature and extent of the interests prejudiced by delay." *TRAC*, 750 F.2d at 80. Mylan has no "right" to an early exclusivity decision for its competitor's ANDA, and forcing FDA to make an early decision would interfere with FDA's own priorities and practice, as described above. There is no reason to believe that Mylan's interest in improved

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[19] Mylan asserts that FDA should "decide now whether the Ranbaxy ANDA has 180-day marketing exclusivity" because "FDA has all of the information it needs to make a decision (and likely has for at least many months)." Mylan Opp. at 18. But Mylan is certainly not privy to what information FDA may or may not have about its competitor's ANDA, or the timing of when FDA may have had such information.

business planning should trump FDA's (and derivatively, the public's) interest in being able to manage its business according to its public health priorities.

Mylan's wish for public information about whether Ranbaxy's atorvastatin ANDA is covered by the AIP, and whether FDA will reject that application (*see* PI Mem. at 23), would prejudice Ranbaxy's right to the confidentiality of information in its ANDA, and FDA's legal responsibility to maintain such confidentiality. Mylan brushes off FDA's concerns about confidentiality as "specious" because "the decision will eventually be announced." Mylan Opp. at 4. But the law expressly requires FDA to maintain the confidentiality of information in and about pending ANDAs, regardless of whether that information may eventually become public upon approval. *See* 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 21 C.F.R. § 314.430, 21 C.F.R. § 20.61. Taken to its logical conclusion, Mylan's argument suggests that FDA could open sensitive information in unapproved ANDA files to public inspection, and yet Mylan itself surely wishes (now) to maintain the confidentiality of information in its own ANDA, even though some of that information may ultimately become public. The relief that Mylan seeks would unduly prejudice these interests (among others), and the fifth factor does not support Mylan's claim of unreasonable delay.[20]

Because there has been no "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," *Hi-Tech*, 587 F. Supp. 2d at 8, Mylan's unreasonable delay claim fails as a matter of law. *See* Compl. ¶ ¶ 67-72 (Count I).[21]

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[20] The sixth *TRAC* factor relates to any "improprieties" behind the alleged delay, and Mylan claims none here. Mylan Opp. at 19.

[21] Mylan has disavowed much of Count II, which alleges arbitrary and capricious action under the APA. *Compare* Compl. ¶ 79 ("Plaintiffs are entitled to a declaratory judgment that FDA

CONCLUSION

For the foregoing reasons and those set forth in Federal Defendant's Memorandum in Support of Motion to Dismiss and in Opposition to Plaintiffs' Motion for Preliminary Injunction, Mylan's complaint should be dismissed for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

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must enforce the AIP and immediately deny Ranbaxy's atorvastatin ANDA if any part of the Ranbaxy ANDA is tainted. . . .") *with* Mylan Opp. at 13 ("If Plaintiffs were asking the Court to require FDA to enforce the AIP against Ranbaxy's atorvastatin ANDA and to deny it, which Plaintiffs are not, Plaintiffs would be seeking to enforce the FDCA against Ranbaxy."). The remaining allegations in Count II largely depend on a "decision" that does not exist, (*see* Compl. ¶¶ 74-76), and may be dismissed on that basis alone, as well as for the reasons described above.

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the Federal Defendant's Reply Memorandum in Support of Motion to Dismiss to be served via the District Court's electronic filing (ECF) system upon:

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