IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS INC., and MATRIX LABORATORIES LTD., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant, and RANBAXY LABORATORIES LTD., Intervenor-Defendant.	Case No. 1:11-cv-00566 (JEB) (UNDER SEAL)

PLAINTIFFS' CONSOLIDATED REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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Douglas B. Farquhar (D.C. Bar No. 386573)
Karla L. Palmer (D.C. Bar No. 444353)
Kurt R. Karst (D.C. Bar No. 482615)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329

Attorneys for Plaintiffs

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INTRODUCTORY STATEMENT

The Defendants in this matter, in their responsive pleadings, miss – or mischaracterize – three key points.

First, the relief which Plaintiffs seek, and which the record demonstrates that the Court should grant, will end the uncertainty and inform other atorvastatin ANDA sponsors (including Plaintiffs) whether they may be permitted to launch generic atorvastatin earlier than May 2012, which is the earliest they can launch if Defendant U.S. Food and Drug Administration ("FDA") reserves a period of marketing exclusivity

for Intervenor-Defendant Ranbaxy Laboratories Ltd. ("Ranbaxy"). The public interest supports allowing generic versions of LIPITOR® to reach market as soon as possible – after Pfizer, the brand manufacturer, has enjoyed 15 years of sales in the U.S. without generic competition – and requiring FDA to give generic manufacturers the information they need to launch successfully.

Second, Matrix's ANDA for atorvastatin is nearing approval by FDA, and FDA lawyers' protestations to the contrary are litigation-driven afterthoughts completely inconsistent with what Plaintiffs have been told by FDA outside the litigation context.

Third, a Citizen Petition filed nearly five and one-half years ago by Pfizer is irrelevant to this matter, and is raised by FDA as a red herring to justify unpardonable delay. Tellingly, the Citizen Petition, which has not been raised by FDA before, does not request that FDA take any specific action or do anything more than consider data and studies that Pfizer provided to FDA along with the petition.

In fact, the issues before the Court are simple and straightforward. Although FDA and Ranbaxy complicate the record and try to deflect attention from the core issues, these and other undisputed facts and circumstances compel an injunction requiring FDA to determine whether Ranbaxy's atorvastatin Abbreviated New Drug Application ("ANDA") is subject to 180 days of marketing exclusivity.

The record in this case demonstrates that:

1. Ranbaxy's Paonta Sahib manufacturing site is subject to FDA's Application Integrity Policy ("AIP"), which, among other things, provides that FDA ordinarily requires withdrawal of drug applications that are tainted by false or unreliable

information. The AIP was imposed more than two years ago and cites reports of unreliable data going back to 2006.

2. Ranbaxy's atorvastatin ANDA has been pending at FDA for nearly nine years.

3. Neither Ranbaxy nor FDA denies that the AIP applies to Ranbaxy's atorvastatin ANDA. If it does, and if Ranbaxy cannot establish that the data in that ANDA are reliable, the application should be withdrawn and Ranbaxy should not be granted 180-day marketing exclusivity for atorvastatin.

4. If Ranbaxy's atorvastatin ANDA is not granted 180-day marketing exclusivity, then generic applicants may be able to obtain approval for their respective applications when certain patent protections expire on June 28, 2011.

Neither FDA nor Ranbaxy raises any persuasive argument why the Agency should not be enjoined to immediately reach a decision – one way or the other – as to whether Ranbaxy's ANDA should be granted exclusivity. Permitting FDA to further delay a decision that it is capable of making now is a disservice to the public and results in depriving the American public, private payors and state and federal governments of potential savings of $3.9 billion to $6.7 billion per year, or $10.9 to $18.3 million per day.

In an effort to avoid Plaintiffs' right to relief here, FDA and Ranbaxy argue in their papers[1] that the Court cannot grant relief that will halt the irreparable harm that is

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[1] FDA's Memorandum in Support of Motion to Dismiss and in Opposition to Plaintiff's Motion for Preliminary Injunction (hereafter, "FDA's Opposition Memorandum") and Ranbaxy's Memorandum of Points and Authorities in Support of Motion to Dismiss and

being caused to Plaintiffs and to the American public and that Plaintiffs do not present a ripe, justiciable claim. The Court must reject these positions.

FDA asserts that the Court should not "interfere" with the Agency's unwarranted delays in determining how to handle Ranbaxy's nearly nine-year-old generic atorvastatin application. FDA does not acknowledge, or simply chooses to ignore, the calamitous effects the Agency's indecision is having and will continue to have on Plaintiffs and other highly interested stakeholders, and on formation of the generic market for atorvastatin. Nor is FDA's position supported by applicable law. FDA's protestations that it cannot disclose whether Ranbaxy retains exclusivity because of the need for confidentiality are specious -- the decision will eventually be announced.

Defendants' attempt to distort the status of Plaintiffs' own atorvastatin ANDA does not alter the reality that compels the relief sought here. After more than two years of extensive review and communications between FDA and Plaintiffs, there are no pending questions from FDA relating to Plaintiffs' atorvastatin ANDA. Supplemental Declaration of S. Wayne Talton ¶¶ 7, 9, 18, attached hereto as Exhibit 1. ("Talton Supplemental Declaration"). Plaintiffs believe, and FDA has not contradicted, that the Matrix ANDA is approvable within the near future. *See id.* ¶¶ 7-9. For these reasons, and because Plaintiffs are irreparably harmed by FDA's failure to disclose whether Ranbaxy's 180-day period of exclusivity will delay the approval of Plaintiffs' ANDA, Plaintiffs have standing to challenge FDA's inaction here.

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in Opposition to Plaintiff's Motion for a Preliminary Injunction (hereafter, "Ranbaxy's Opposition Memorandum").

Therefore, based on the record before the Court, the Court should deny the Motions to Dismiss and grant Plaintiffs' Motion for Preliminary Injunction.

ARGUMENT

I. Plaintiffs Have Standing to Bring This Action, and Their Claims Are Ripe for Judicial Consideration

Defendants argue that Plaintiffs do not have standing because Plaintiff Matrix has not received a tentative approval from FDA for its atorvastatin ANDA.[2] They also argue that this matter is not justiciable because there is no final agency action that can be reviewed by the Court. But this misses the point – Plaintiffs seek relief from this Court precisely because there has been no agency action on an issue of critical importance. As demonstrated below,[3] Plaintiffs plainly have established a concrete injury in fact. Final agency action, under the circumstances presented here, is not required to establish standing.

a. Matrix's ANDA Is on a Clear and Reliable Path to Approval

Courts have recognized repeatedly that generic drug manufacturers – like Plaintiffs – have standing to protect their rights to launch generic drugs early in the formation of the generic market, and to prevent competitors from receiving unlawful grants of marketing exclusivity. *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311-12 (D.C. Cir. 2010); *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 45-47 (D.D.C. 2000); *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1346-48 (Fed.

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2 Ranbaxy's Opposition Memorandum at 14; FDA's Opposition Memorandum at 15.

3 This Memorandum consolidates a reply memorandum with a memorandum in opposition, so the page limits of the Local Rules permit a maximum length of 70 pages, well in excess of the number of pages of this memorandum.

Cir. 2010), *petition for cert. filed*, 2011 WL 720842 (U.S. Feb. 25, 2011). And, contrary to Defendants' argument, courts do not require drug manufacturers to have a tentative approval to bring a lawsuit against FDA to protect their rights to launch generic drugs, or to launch a generic drug with exclusivity.

Although the lack of a tentative approval has occasionally been viewed as a factor in determining whether a plaintiff has standing, in numerous decisions, tentative approval is not a predicate for an ANDA sponsor to have standing to challenge FDA (in)action on exclusivity or issues concerning a competitor's ANDA approval. *See Pfizer v. Shalala,* 182 F.3d 975, 980 (D.C. Cir. 1999) (noting without objection that intervenor Mylan's ANDA had not received tentative approval until after oral argument on appeal); *see also Purepac Pharm. Co. v. Thompson,* 238 F. Supp. 2d 191 (D.D.C. 2002) (FDA records show that Purepac did not receive a tentative approval, and received final approval in September 2003, and intervenor Apotex did not receive tentative approval until December 2002, after the Complaint was filed and standing could have been challenged), *aff'd sub nom. Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877 (D.C. Cir. 2004); *Teva Pharms., USA, Inc. v. FDA*, 1999 WL 1042743 (D.D.C. Aug 19, 1999) (FDA records show that TorPharm did not receive a tentative approval until April 1999, well after preliminary injunction proceedings in January 1999, when standing could have been challenged; intervenor Invamed likewise did not receive a tentative approval until May 1999), *aff'd*, 254 F.3d 316 (D.C. Cir. 2000); *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69 (D.D.C. 2003) (same approvals discussed in *Purepac* above), *aff'd*, 354 F.3d 877 (D.C. Cir. 2004). Requiring a plaintiff to have a tentative approval in order to seek relief

such as that requested under the circumstances here would mean that FDA could never be held accountable for its delay in rendering a decision. Such a result well oversteps the bounds of any deference owed to FDA, particularly where FDA's inaction, as here, detrimentally impacts Plaintiffs and the public.

Indeed, this point is particularly relevant since tentative approval is not a prerequisite to final approval and it is by no means commonplace that ANDA sponsors receive tentative approvals. Even a cursory comparison of the list of tentative approvals cited in the FDA brief (FDA's Opposition Memorandum at 11) with the list of approved drugs posted by FDA itself [4] shows that dozens of recent ANDA drugs proceeded to final approval without receiving a tentative approval, although many, presumably, would have qualified for tentative approval. With these drugs, as with atorvastatin, requiring an ANDA sponsor to have received a tentative approval prior to seeking court review of an FDA decision (or, as in this case, the lack of a decision) would insulate FDA from adequate, timely judicial review. This is because, when FDA does issue a tentative approval to a generic drug manufacturer, and if FDA will not grant final approval to that manufacturer because it is reserving a period of marketing exclusivity for a competitor, the tentative approval will uniformly say so, if that is what is blocking final approval. Therefore, if FDA desired to avoid court review of the timeliness of its decision on marketing exclusivity, it could simply delay granting any tentative approvals, and then

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[4] *See* Food and Drug Administration, Center for Drug Evaluation and Research, Drug Approval Reports, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=ReportsMenu.

argue any court challenge is therefore not ripe for judicial consideration (as it has apparently done here).

Contrary to Defendants' position, what is required to establish standing is that the "plaintiff allege an actual or imminent injury that is fairly traceable to the defendant's challenged conduct and redressable in the judicial proceeding." *Teva,* 595 F.3d at 1312 (citation omitted). Matrix and Mylan more than meet that test.

As established in Plaintiffs' Opening Memorandum, Plaintiffs have not been informed by FDA of "any open deficiencies with the Matrix ANDA." Talton Declaration ¶ 11 (attached to Plaintiffs' Memorandum in Support of Motion for a Preliminary Injunction ("Plaintiffs' Opening Memorandum")) (filed under seal); Talton Supplemental Declaration ¶¶ 7-10, 18 (filed under seal).

FDA's own submission, attached under seal as Exhibit D to its Opposition, confirms many of the points also made in Talton's Initial and Supplemental Declarations. [redacted] The last questions that FDA posed have been answered. FDA promises in its unsworn Exhibit D and in its brief that it is conducting a review of Matrix's ANDA and other atorvastatin ANDAs in as expeditious a manner as possible, but it has not yet issued tentative approvals on any of the atorvastatin ANDAs. As discussed below, this delay has occurred even though the Hatch-Waxman Amendments require action on an ANDA within 180 days, absent agreement of the parties, and even though at least one ANDA (namely, Ranbaxy's) has been pending for, as the government admits, nearly nine years.

FDA's Opposition Memorandum at 16. FDA has all the information it needs to approve the Matrix ANDA.

FDA drops into its brief arguments about the [redacted] [redacted] *Id.* at 15-16. However, FDA has already determined that Matrix's product is [redacted] *See* Talton Supplemental Declaration ¶ 9; FDA Ex. D at 1. Furthermore, FDA's attempt to rely on a November 2005 Pfizer Citizen Petition to support its standing and ripeness arguments and as a basis for delaying approvals is unavailing and should be rejected. FDA's Opposition Memorandum at 15, 18. Pfizer's Citizen Petition – Docket No. FDA-2005-P-0315 (formerly FDA Docket No. 2005P-0452) – requests that FDA consider in its review of atorvastatin ANDAs information about "physical forms of atorvastatin that may be susceptible to higher levels of impurities than are found in Lipitor. . . ." Pfizer Citizen Petition, Ex. B to FDA's Opposition Memorandum at 1. In the Citizen Petition, Pfizer did not request that FDA take any specific action or do anything more than consider data and studies that Pfizer provided to FDA along with the petition. Pfizer did not request that FDA reject atorvastatin ANDAs of the polymorphic versus crystalline form of the product, or that FDA conduct additional or special studies related to the form of the product.

In the almost five and one-half years -- since November 7, 2005 (or at least 1,982 days) -- since the Pfizer petition was submitted to FDA, and in the more than two years since the Matrix ANDA has been pending at FDA, not once has FDA indicated to Matrix or Mylan – or to the public – that the citizen petition will serve as a barrier to approval (either tentative or final) of any atorvastatin ANDA, much less that of Matrix. Talton

Supplemental Declaration ¶¶ 12, 15-16. Although FDA's May 2006 tentative response to the citizen petition states that the petition "raises complex issues requiring extensive review and analysis by Agency officials,"[5] the language is mere boilerplate. The citizen petition responses that contain this language are legion, and can be found by using the website where the responses are made available to the public.[6] Indeed, as the Talton Supplemental Declaration makes clear, Plaintiffs have received no inquires from FDA, and FDA has voiced no concerns to Plaintiffs relating to the content of the Pfizer citizen petition. Talton Supplemental Declaration ¶¶ 11, 15, 17.

Only now, when FDA is faced with this action, and after many years during which FDA surely must have thoroughly considered the issues raised in the citizen petition, does FDA raise the petition in an eleventh-hour, post-litigation attempt to explain away

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5 FDA's Opposition Memorandum at 15.

6 For some recent examples, *see* Letter from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA, to Kumar Sekar, Ph.D., Dr. Reddy's Laboratories, Inc. (Feb. 11, 2011), *available at* http://www.regulations.gov/#!documentDetail; D=FDA-2010-P-0438-0003; Letter from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA, to J. Michael Nicholas, Ph.D., Senior Director, Strategic Regulatory Affairs, Teva Neuroscience, Inc. (Dec. 13, 2010), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0317-0003; Letter from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA, to Bruce Manheim, Jr. and Joy Liu, Ropes and Gray LLP (Jun. 4, 2010), *available at* http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480afef88&disposition=attachment&contentType=pdf; Letter from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA, to Sandra Rattray, Vice President, Regulatory Affairs - Oncology, Ortho-Biotech Products, L.P. (Oct. 30, 2009), *available at* http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480a4fddc&disposition=attachment&contentType=pdf; *see, e.g.,* Letter from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA, to Jeffrey Jonas, MD, Senior Vice President, Research and Development, Shire Pharmaceuticals, Inc. (Mar. 9, 2009), *available at* http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480906659&disposition=attachment&contentType=pdf.

the Agency's inaction. The sudden and unexpected trumpeting by FDA about the citizen petition filed long ago cannot possibly be deemed to introduce a brand new and inappropriate obstacle to approval of atorvastatin ANDAs. Apparently feeling emboldened, FDA even throws in a "kitchen sink" statement that "[a]ny number of other not publicly identifiable scientific and technical issues could also potentially stand as a barrier to tentative approval of Mylan's ANDA." FDA's Opposition Memorandum at 16. Such speculation is not supported by FDA's actions or its review thus far of the Matrix ANDA. Talton Supplemental Declaration ¶ 8, 17-19.

Also, FDA counsel's speculations that the Pfizer petition could serve as a basis to delay approval of atorvastatin ANDAs is at odds with Congress' intent in enacting 21 U.S.C. § 355(q), which requires FDA to make final decisions on citizen petitions relating to certain drug approvals within 180-days after the petition is submitted and prohibits FDA from delaying approval of a pending ANDA because of a citizen petition (except in very limited circumstances). Although Pfizer's citizen petition, submitted to FDA in 2005, is not subject to the 180-day statutory deadline Congress established in September 2007 under 21 U.S.C. § 355(q), the petition should not be used by FDA as a basis to subvert the timely approval of ANDAs or as an excuse for FDA's inaction here. *See* 153 Cong. Rec. S11938 (daily ed. Sept. 21, 2007) (statement of Sen. Kennedy) (stating that the citizen petition process "should be used to protect public health – but too often, it is subverted by those who seek only to delay the entry onto the market of generic drugs.").

Therefore, Plaintiffs have demonstrated that they have a strong and reasonable expectation that the Matrix ANDA (or other atorvastatin ANDA sponsors) will receive FDA clearance, and have shown that FDA's inaction is causing real, concrete injury that leads them to present a ripe "case or controversy" to the Court. FDA's professed fear of opening the floodgates to litigation of this type – drug approval applicants seeking court orders requiring FDA to issue timely decisions – is far fetched, given the uniqueness of the situation here: (1) an ANDA pending for more than eight and one-half years; (2) for a drug with a potential generic market approaching the size of generic atorvastatin; and (3) FDA having invoked the AIP against a potential competitor more than two years earlier, with no decision as to whether FDA will enforce the AIP. Furthermore, as FDA nearly concedes,[7] exclusivity periods for any ANDAs submitted after the 2003 enactment of the Medicine Modernization Act ("MMA") would likely have been extinguished by now.

b. Plaintiffs' Claims Are Justiciable.

As noted above, there are numerous cases from this Court and from this Circuit 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. The prior section of this Memorandum demonstrated that the case presented to the Court is ripe. Defendants' remaining standing argument relates to the justiciability of the Plaintiffs' claims.

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[7] FDA's Opposition Memorandum at 7.

Plaintiffs' claims are properly reviewable by this Court. FDA is creating a straw man when it argues that Plaintiffs' claims violate the well-accepted doctrine that there is no private right of enforcement under the Federal Food, Drug, and Cosmetic Act ("FDCA"). FDA's further argument that it is entitled to set its own schedule, no matter how lengthy, in determining Ranbaxy's eligibility for marketing exclusivity, without "judicial interference,"[8] is nowhere supported in the FDCA, is directly contradicted by the Administrative Procedures Act ("APA") and the case law, and creates serious injustice to the consuming public who rely on less expensive generic drug products.

Arguably, 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.[9] But, here, what Plaintiffs are seeking is simply a timely decision on Ranbaxy's eligibility for marketing exclusivity. In doing so, Plaintiffs are not seeking an order that FDA enforce the AIP against Ranbaxy. Rather, Plaintiffs are asking the Court to order FDA to comply with the law in issuing a decision because that decision is unlawfully long overdue.

FDA argues, basically, 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. FDA's Opposition Memorandum at 28-29. Nowhere in the

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8 *Id.* at 2.

9 Of course, this argument is not an admission that, if FDA ultimately issues an arbitrary and capricious (or otherwise unlawful) decision on Ranbaxy's ANDA, that decision would be immune from judicial review. As Ranbaxy admits, once the decision is issued, "Any applicant that disagrees with FDA's decision may challenge FDA's decision in court at that time." Ranbaxy's Opposition Memorandum at 5.

FDCA is there support for the proposition that FDA can take nearly nine years to determine whether an ANDA is approvable. Although the FDCA does permit the 180-day review limit to be extended based on an agreement of the parties, where the determination of the approvability of an ANDA is complicated by the fraud of the first ANDA applicant and could stall generic market formation, as here, delay of this magnitude (approaching 18 times the statutory goal) is directly contradictory to the intent of the Hatch-Waxman Amendments to enable speedy generic drug entry to the market. Furthermore, APA provisions governing administrative delay make no exceptions for ANDA decision-making. Nor does the FDCA. As the case law under the APA holds, in the absence of provisions permitting extensive delays, courts are empowered to review agency delay to determine whether it is "unreasonable," or "unlawful." *See, e.g., In re American Rivers and Idaho Rivers United,* 372 F.3d 413 (D.C. Cir. 2004) (six-year delay in responding to petition was egregious and thus Court granted petitioners' relief under the APA); *Telecommunications Research and Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) (*"TRAC")* (agencies should act within a reasonable period of time; courts play an important statutory role in compelling agency action that is improperly withheld or unreasonably denied); *Sandoz v. Leavitt,* 427 F. Supp. 2d 29 (D.D.C. 2006) (court held FDA's failure to approve plaintiff's application or grant a hearing after 1000 days was unreasonable and egregious).

Therefore, Plaintiffs' claims are justiciable.

II. FDA'S Unlawful Delay in Deciding Whether the AIP Extinguishes Ranbaxy's 180-Day Market Exclusivity is Egregious.

Plaintiffs seek an order from this Court addressing FDA's arbitrary, capricious and unreasonable failure to make a decision as to whether Ranbaxy's ANDA is subject to 180-day marketing exclusivity. FDA has all of the information it needs to make this decision now.

Defendants admit that Ranbaxy's ANDA has been pending with FDA for nearly nine years, and that Ranbaxy's ANDAs related to the Paonta Sahib site have been subject to the AIP for more than two years. Defendants do not deny that the Ranbaxy atorvastatin ANDA is subject to the AIP. Therefore, the delay occasioned here is, in fact, egregious, especially in light of the goal set forth in the Hatch-Waxman Amendments that decisions on ANDAs be issued within 180 days.

Relying on *TRAC*, FDA claims that Plaintiffs fail to state a claim for unreasonable delay because FDA's delay in issuing a decision on Ranbaxy's exclusivity is not sufficiently "egregious" to warrant relief. FDA's Opposition Memorandum at 28-29. While FDA fails to offer an analysis of these factors, *TRAC* in fact establishes useful factors for this Court to consider when making a determination whether agency delay is unreasonable. Consideration of these factors demonstrates that Plaintiffs have established that FDA has failed – egregiously – to act in this case.

The D.C. Circuit held in *TRAC* that "[5 U.S.C.] section 706(1) coupled with [5 U.S.C.] section 555(b) does indicate a congressional view that agencies should act within reasonable time frames and that court's [sic] designated by statute to review agency actions may play an important role in compelling agency action that has been

improperly withheld or unreasonably delayed." 750 F.2d at 77. As provided in *TRAC*, the six-part standard for "assessing claims of agency delay" includes the following: (1) "the time agencies take to make a decision 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 effect of expediting delayed action on "agency activities of a higher or competing priority;" (5) "the nature and extent of the interests prejudiced by delay;" and (6) "the court need not 'find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'" *Id.* at 80 (citations omitted). As demonstrated below, these factors weigh heavily in favor of compelling FDA to make a decision in this case.

As for the first and second *TRAC* factors, which involve the "timing" of an agency decision, *id.*, the Hatch-Waxman Amendments plainly mandate that FDA complete its review and approve or disapprove an ANDA within 180 days after FDA receives an application. 21 U.S.C. § 355(j)(5)(A); *see also* 21 C.F.R. § 314.100 ("within 180 days of receipt of . . . an abbreviated application for a new drug under section 505(j) of the act, FDA will review it and send the applicant either an approval letter under § 314.105 or a complete response letter under § 314.110.").[10] Moreover, FDA's failure to act on

[10] FDA regulations provide that this time period can be changed by mutual agreement of the parties. 21 C.F.R. § 314.100(c).

Ranbaxy's ANDA and the associated exclusivity period within anything remotely close to these time limits defeats the "central purpose" of the Hatch-Waxman Amendments, which is "'get[ting] generic drugs into the hands of patients at reasonable prices - fast.'" *See Shalala,* 81 F. Supp. 2d at 41 (citation omitted).

Considering the more than eight and one-half years that the Ranbaxy ANDA has been pending, the more than two years since FDA invoked the AIP against Ranbaxy's Paonta Sahib manufacturing site, and the requests made by Plaintiffs that FDA make a decision but FDA did nothing, FDA's failure to act here, in terms of the length of delay, is beyond any "rule of reason," and indeed egregious.

As for the third *TRAC* factor, which involves consideration of whether "human health and welfare are at stake," *TRAC*, 750 F.2d at 80, the launch of generic atorvastatin is unprecedented in terms of its scope and impact on public health and welfare. As the *Sandoz* court, citing *In re Barr Labs,* 930 F.2d 72, 75 (D.C. Cir. 1991), holds, "swift approval of new drugs certainly benefits the public health and welfare." 427 F. Supp. 2d 29, 38-39 (D.D.C. 2006). FDA's delay also delays and hinders access of the American public to a generic version of one of the most widely-prescribed branded drugs. FDA's arbitrary failure to make a decision injures consumers and government payors, and thwarts Hatch-Waxman's goal of getting drugs into the "hands of patients . . . fast."[11] *See* Plaintiffs' Opening Memorandum at 31; Mauro Declaration ¶¶ 15-16 (attached to Plaintiffs' Opening Memorandum). Public health and welfare likely are imperiled by FDA's arbitrary failure to make a decision, because it is precisely that indecision that will

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[11] *Shalala,* 81 F. Supp. 2d at 41.

keep atorvastatin out of the hands of those who cannot afford brand-name LIPITOR®. FDA's delay also causes significant and irreparable economic harm to Plaintiffs. FDA's Opposition Memorandum at 2 ("the prospect of being an early generic entrant for LIPITOR is certainly worth a great deal of money").

For the same reasons as discussed with the third factor, the fourth factor ("the effect of expediting delayed action on agency activities of a higher or competing priority," *TRAC,* 750 F.2d at 80), is satisfied here. In addition, Plaintiffs are not asking the Court to force FDA to "expedite" its decision as all. Mylan's request is much simpler. Given that FDA has all of the information it needs to make a decision (and likely has for at least many months),[12] this Court should require FDA to decide now whether the Ranbaxy ANDA has 180-day marketing exclusivity, particularly in view of the expiration of certain patent exclusivity for LIPITOR®. *See, e.g., Biovail Corp. v. FDA,* 519 F. Supp. 2d 39 (D.D.C. 2007) (the "public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible") (citing *Boehringer Ingelheim Corp. v. Shalala,* 993 F. Supp. 1, 3 (D.D.C.1997)); *Schering Corp. v. Sullivan,* 782 F. Supp. 645, 652 (D.D.C. 1992) (a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices").

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12 The FDA median time to approval of an ANDA submitted by any company is approximately 31 months after submission. The median approval time for Mylan's 154 prior ANDAs varied, but was in the range of between [redacted] months each year from 2005 to 2010. Talton Supplemental Declaration ¶¶ 2-4. Therefore, the 28 months that it has taken FDA to consider Mylan's atorvastatin ANDA is well in excess of the median for most of its ANDAs, regardless of whether it is shorter than the median ANDA approval time for most companies.

As for the fifth factor ("the nature and extent of the interests prejudiced by delay," *TRAC*, 750 F.2d at 80), it is abundantly clear that Plaintiffs, the American public, and government payors are all prejudiced by the FDA's delay in making a decision. As set forth in Plaintiffs' Opening Memorandum and the attached Declarations, delay affects American consumers in terms of significant lost savings and in terms of being denied access to cheaper, generic forms of atorvastatin. The government also could save between $1.3 and $2.3 billion in the first year after the launch (Mauro Declaration ¶ 15 (attached to Plaintiffs' Opening Memorandum)). Plaintiffs' interests are likewise prejudiced by FDA's delay, since Mylan has already sustained losses of market share, irrecoverable consumer goodwill and lost transactions for other products due to manufacturing diversion. *See* Mauro Declaration ¶ 20; Babu Declaration ¶¶ 23-27 (under seal). FDA's interests, however will not be prejudiced by an order from this Court requiring FDA to act after it has failed to do for so many years.[13]

Asserting that its delay is not egregious, FDA argues that "resolving the exclusivity issue in this case will not be straightforward." FDA's Opposition Memorandum at 30. This argument sounds eerily similar to FDA's claim in *Sandoz v. Leavitt*, 427 F. Supp. 2d 29, 32 (D.D.C. 2006), that FDA's delay in trying to determine whether to approve the Plaintiffs' version of Omnitrope was due to the "nature and complexity" of the application, a claim that the court rejected in ruling against FDA. FDA's argument flies in the face of the fact that FDA has had in excess of two years to

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[13] As to the sixth *TRAC* factor, Plaintiffs have not claimed any "improprieties" behind the Agency's inexplicable failure to make a decision here; but according to *TRAC,* this Court is not required to make such a finding.

review the "exclusivity issue." FDA invoked the AIP against Ranbaxy and issued warning letters to Ranbaxy concerning manufacturing practices at its Paonta Sahib site as far back as 2006. *See* Letter to Mr. Malvinder Mohan Singh, Ranbaxy Laboratories, Ltd., from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA, dated February 25, 2009, invoking the AIP, ("February 2009 Letter"), attached to Plaintiffs' Opening Memorandum, Declaration of Karla Palmer, Exh. C. Based on the February 2009 Letter invoking the AIP against Ranbaxy, FDA (and Ranbaxy) know exactly what ANDAs contain tainted data, and FDA knows what, pursuant to the AIP, it must do to resolve the "exclusivity issue" now, but FDA has arbitrarily and capriciously failed to act.

In short, consideration of the *TRAC* factors applied to undisputed facts leads to only one conclusion: FDA's delay has been and continues to be egregious. Therefore, the Court should order FDA to make a decision concerning whether the Ranbaxy ANDA has 180-day marketing exclusivity.

Other cases cited by Defendants are no more helpful to their arguments. Defendants are correct that, in *Norton v. Southern Utah Wilderness Alliance,* the Supreme Court determined that 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. Southern Utah Wilderness Alliance,* 542 U.S. 55, 64 (2004) (emphasis in original). The Court elaborated, however, that "when an agency is compelled by law to act within a certain time period, but the manner of its action is left to the agency's discretion, a court can compel the agency to act, but has no power to specify what that

action must be." *Id.* at 65. That is exactly what Plaintiffs seek here. Plaintiffs request an order from this Court requiring FDA, after years of wrongful delay, to determine whether or not the Ranbaxy ANDA has 180-day exclusivity pursuant to 21 U.S.C. § 355(j)(5)(A), 21 C.F.R. § 314.100 and the AIP. Plaintiffs are not requesting this Court to determine "what that action must be." *See id.* After all, FDA was statutorily required to issue a decision on Ranbaxy's ANDA within 180 days of its submission. Although Plaintiffs recognize that that time limit may be extended by agreement of the parties, extending that limit by 18 times (or eight and one-half years), and also waiting in excess of two years after imposition of the AIP to decide whether the Ranbaxy ANDA receives 180-day marketing exclusivity is inconsistent with the law (21 U.S.C. § 355(j)(5)(A), 21 C.F.R. § 314.100) and the plain mandate of the Hatch-Waxman Amendments to get generic drugs on the market as soon as possible.[14] Of course, 18 times the statutory goal is well in excess of the five times the statutory requirement that the *Sandoz* court found to be "egregious." *Sandoz,* 427 F. Supp. at 40.

Similarly, Defendants' reliance on *In re American Rivers and Idaho Rivers United,* 372 F.3d 413 (D.C. Cir. 2004) is misplaced. In that mandamus action, the court applied the *TRAC* factors to determine whether compelling FERC to answer a petition was unreasonable. The court found the agency's delay of six years was unreasonable.

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[14] The MMA similarly amended Hatch-Waxman to prevent exclusivity-eligible generic applicants from unduly delaying their entry into the market (or "parking" exclusivity) by the addition of several exclusivity forfeiture provisions to the statute. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I). The forfeiture provisions of the MMA were added to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer).

Citing 5 U.S.C. §§ 555(b) and 706(l) , the court held, "There is 'no *per se* rule as to how long is too long' to wait for agency action, . . . but a reasonable time for agency action is typically counted in weeks or months, not years." *Id.* at 419 (citation omitted) (emphasis in original). In this case, FDA has waited *years*, not weeks or months to act, rendering FDA's delay unreasonable by any measure.

In another mandamus case cited by Defendants, *In re Bluewater Network,* 234 F.3d 1305 (D.C. Cir. 2000), plaintiffs sought a petition for a writ of mandamus requiring the Coast Guard to engage in a rulemaking on two issues. The court granted plaintiffs' mandamus petition on one of the issues where a nine-year delay was unreasonable in light of a "clear one-year time line" to act. *Id.* at 1316. Here, FDA has failed to act in the almost nine years since Ranbaxy filed its ANDA, and two years after FDA invoked the AIP. Such delays are directly contrary to the clear mandate of the Hatch-Waxman Amendments, which does not permit FDA to delay indefinitely making a decision. 21 U.S.C. § 355(j)(5)(A); 21 C.F.R. § 314.100. FDA's unreasonable delay is causing irreparable harm to Plaintiffs, the government and the public.

Lastly, the district court's decision in *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008), relied upon by the Defendants, is not binding on this Court[15] and is readily distinguishable from this case. There, Hi-Tech sought to block

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15 "District Court decisions do not establish the law of the circuit . . . nor, indeed, do they even establish 'the law of the district.'" *In re Executive Office of the President*, 215 F.3d 20, 24 (D.C. Cir. 2000) (citing *City Stores Co. v. Lerner Shops*, 410 F.2d 1010, 1014 (D.C. Cir. 1969) and *Threadgill v. Armstrong World Indus., Inc.*, 928 F.2d 1366, 1371 (3d Cir. 1991)); *see also Fox v. Acadia State Bank*, 937 F.2d 1566, 1570 (11th Cir. 1991) ("A district court is not bound by another district court's decision, or even an opinion by another judge of the same district court").

FDA from approving any competitor's ANDA during the period of Hi-Tech's marketing exclusivity. The court's decision hinged on the fact that "FDA ha[d] not yet construed or applied the forfeiture provisions in this case" to determine whether any competitor's drug would be approved, and thus it was premature to prevent FDA from granting approval to competitors. In contrast, Plaintiffs' case here does not seek to block approval of any competitors; indeed, Plaintiffs only ask that FDA make a decision (one way or the other) after years of unreasonable delay, concerning whether the Ranbaxy ANDA has marketing exclusivity.

III. Continuing FDA Delay Will Cause Plaintiffs Irreparable Harm.

Defendants attempt to minimize Plaintiffs' harms as "merely" economic and insufficient to justify court intervention. However, Plaintiffs have demonstrated that their harm extends beyond economic loss. Plaintiffs also face irreparable harm in unquantifiable losses of market share, goodwill, and access to customers. *See CollaGenex Pharms., Inc. v. Thompson*, 2003 WL 21697344, *10 (D.D.C. 2003) (holding that foreseeable market share drop constituted irreparable harm); *Hoffman-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978) (holding that a "loss of sales and good will" was not a "mere economic" injury and was "irreparable"); *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002) (loss of market share constituted irreparable harm because it "cannot be redressed by a legal or an equitable remedy following a trial") (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989)); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, 2010 WL 2516465, at *11

(D.N.J. 2010) ("the loss of goodwill . . . is the type of injury that is the definition of 'irreparable'") (quoting *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 391 (2006)).

These harms are compounded by the fact that Plaintiffs can have no later recourse against FDA. *See CollaGenex*, 2003 WL 21697344, at *10 ("[w]hile the injury to plaintiffs is 'admittedly economic,' there is 'no adequate compensatory or other corrective relief' that can be provided at a later date, tipping the balance in favor of injunctive relief") (quoting *Hoffman-Laroche*, 453 F. Supp. at 903); *see also Bracco Diagnostics, Inc., v. Shalala,* 963 F. Supp. 20, 28-29 (D.D.C. 1997); *Torpharm*, 1997 WL 33472411, at *4 (irreparable injury is shown where plaintiff "will suffer an injury for which there is no remedy at law").

Furthermore, FDA's failure to make a decision as to whether Ranbaxy has exclusivity could preclude Plaintiffs from competing adequately in the atorvastatin market for an indeterminate period of time. In this Circuit, preclusion from market participation is considered irreparable harm. *See Bracco Diagnostics,* 963 F. Supp. at 29 ; *see also Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130-31 (D.D.C. 1997); *Torpharm v. Shalala*, 1997 WL 33472411, *4 (D.D.C. 1997) (timely entry to the market is "critical" to success and, consequently, delay of entry was irreparable harm). Where, as here, that preclusion bars timely participation in the most profitable generic drug launch in history, irreparable harm which Plaintiffs face is surely "serious." *Gulf Oil Corp. v. Dep't. of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981).

The irreparable harm that Plaintiffs are already suffering as a result of FDA's delayed decision on Ranbaxy's exclusivity is two-fold: First, Plaintiffs are being forced

to invest tens of millions of dollars in order to participate in a market where they may be denied entry until May 2012 or later (thus, investments will be wasted if Ranbaxy is granted exclusivity). Second, Plaintiffs cannot adequately prepare to meet market demand in a market that they would be able to occupy earlier, if Ranbaxy is denied exclusivity. Indeed, this irreparable harm, preventable by Court Order, only exacerbates the same types of harm that Mylan has suffered and that could be prevented if FDA makes its decision soon.

Ignoring cases in which injunctive relief has issued on substantially less harm than Plaintiffs are suffering here, FDA asserts Plaintiffs must show a threat to "the continued existence of [their] business" to show irreparable injury. However, the authority cited by FDA is inapposite. FDA dismisses Plaintiffs' need to make business decisions in an uncertain environment as merely the nature of doing business, and sidesteps the crucial fact that the unique circumstances here and the uncertainty is the product of FDA's own *unlawful* delay. Given the shortness of time, Plaintiffs will now only be *able* to compete for a smaller percentage of the market than they might have obtained if FDA issued its decision on Ranbaxy's exclusivity earlier [redacted] percent as opposed to the [redacted] percent normally targeted). *See* Declaration of Dr. Hari Babu ¶ 14 (attached, under seal, to Plaintiffs' Opening Memorandum); Declaration of Anthony Mauro ¶ 20 (attached to Plaintiffs' Opening Memorandum). The [redacted] percent differential is equivalent to a very significant portion of Mylan's annual revenue. (The [redacted] of projected revenue already estimated to have been lost is equivalent to [redacted] of Mylan's current annual revenue; *see* Mauro Declaration ¶ 20 (attached to Plaintiffs' Opening Memorandum).

In contrast to enormous damages caused by FDA's egregious multi-year delay here, in *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 123 (D.D.C. 2007), cited by Defendants, the court noted that movants stood to lose only relatively insignificant amounts in comparison to their overall finances. Here, however, Mylan conservatively estimates it has already lost an amount equaling about [redacted] percent of its projected revenue for a 12-month period (approximately [redacted]), if FDA decides, as it should, that Ranbaxy is not entitled to marketing exclusivity. Mauro Declaration ¶ 20. Those losses are in addition to lost sales of other drugs caused by diversion of production, and unquantifiable damages to goodwill, customer access, and existing markets for other drugs. Mauro Declaration ¶ 11; Babu Declaration ¶¶ 10, 25-26. Plaintiffs can hope to regain some of that market share only if FDA promptly makes a decision in this case.

Moreover, Plaintiffs' anticipated losses here differ starkly from those alleged in cases FDA cites to show a need for "extreme hardship." *See Apotex, Inc. v. Food and Drug Administration*, 2006 WL 1030151 (D.D.C. 2006) (finding no irreparable harm where movant's losses equated to about one percent of its annual revenues); *Bristol-Myers Squibb Company v. Shalala*, 923 F. Supp. 212 (D.D.C. 1996) (finding loss equating to 0.7 percent of sales was not irreparable injury); *Shalala*, 81 F. Supp. 2d at 43 (finding loss of 0.4 percent of annual sales did not "constitute irreparable harm").

To minimize Plaintiffs' harm from FDA's inaction, FDA attempts to equate Plaintiffs Mylan Pharmaceuticals Inc. (which operates exclusively in the United States) and Matrix, with Mylan Inc., a separate, and much larger, international corporate entity. FDA cites absolutely no authority for this bold effort to pierce the corporate veil. "It is,

of course, hornbook law that a duly-formed corporation enjoys a separate legal existence from its shareholders and that shareholders have no specific interest in corporate property." *Sacks v. Rothberg*, 861 F.2d 1290 (D.C. Cir. 1988). The revenues of non-party Mylan Inc., the exclusive shareholder of its U.S. operating subsidiary, Plaintiff Mylan Pharmaceuticals Inc., are irrelevant in terms of judging harm to that subsidiary. Notably, in *Sandoz, Inc. v. Food and Drug Administration*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006), the only case Plaintiffs found that mentions the revenues of a plaintiff's parent corporation, the court decided the issue of irreparable harm by examining the relationship of the plaintiff's projected losses to its own sales revenues, not to the revenues of its large corporate parent. The Court should do the same here.

Moreover, as explained in Plaintiffs' Opening Memorandum, FDA's delay likewise harms Plaintiffs if FDA decides to grant Ranbaxy exclusivity, and that determination is upheld on approval. Tens of millions of dollars in necessary investments to prepare for launch will be lost if Mylan's launch. And Matrix can never regain the revenue from lost sales of products that FDA's indecision has forced Matrix to displace in order to manufacture sufficient atorvastatin to meet generic market demand.

IV. The Public Interest Favors Requiring FDA to Issue Its Decision on Ranbaxy's Exclusivity Period Soon.

In a weak attempt to counter the overwhelming evidence (the majority of which is conceded by the Defendants) that entry of generics to the market benefits the public interest, Defendants argue, on different bases, that ordering FDA to make a decision now about Ranbaxy's marketing exclusivity will harm the public interest. Nothing could be further from the truth, and, indeed, Defendant's unrealistic characterization of the public

interest demonstrates why action by this Court is necessary to truly protect the public interest.

Ranbaxy unconvincingly argues that any threat to its alleged "right" to exclusivity would disincentivize first filers from challenging brand patents. Ranbaxy's Opposition Memorandum at 1, 16. Ranbaxy mischaracterizes the factual background of this case by stating that Plaintiffs have done "nothing" to open up the market to generic competition. *Id.* at 1. In fact, as Ranbaxy well knows and FDA admits,[16] Plaintiffs, as well as other ANDA filers, have engaged in their own, expensive patent litigation with the LIPITOR® brand manufacturer, Pfizer. Furthermore, requiring FDA to act without further delay on the exclusivity of an ANDA nearly nine years after that ANDA was filed, and more than two years after FDA invoked the AIP against it, would hardly be something that ANDA holders would calculate as an issue in determining whether to challenge a patent, especially since provisions governing any ANDA filed after the effective date of the MMA amendments virtually guarantee that no ANDA of a first filer would be entitled to exclusivity this long after the ANDA was filed.[17] Additionally, the public interest would not be served by awarding Ranbaxy 180-day exclusivity based on an ANDA that, if true,

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16 FDA's Opposition Memorandum at 12.

17 The MMA amended the Hatch-Waxman Amendments by the addition of various forfeiture provisions that prevent ANDA sponsors eligible for 180-day exclusivity from delaying generic entry into the market by "parking" their exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i). One of those forfeiture provisions provides that 180-day exclusivity eligibility is forfeited if the first applicant fails to obtain tentative approval of their ANDA within 30 months of submission, except in circumstances not relevant here. *Id.* § 355(j)(5)(D)(i)(IV). Thus, the delay to market in this case caused by FDA's failure to make a decision on first-filer Ranbaxy's ANDA likely will not happen in another case because, if the MMA had applied (e.g., post-December 8, 2003 ANDA submissions), Ranbaxy would have lost any exclusivity within 30 months after it submitted its ANDA.

is tainted by bad data, which would only serve to reward the bad actor by causing damage to its competitors.

FDA argues that the public interest is assaulted when a court dares to question its timetable in reviewing ANDAs, since, apparently, "scientific issues remain to be resolved" even though it is nearly nine years after Ranbaxy's application was filed. FDA's Opposition Memorandum at 41. This is not true. In addition, FDA's professed concern about maintaining the confidentiality of the ANDA is irrelevant. At some point, presumably, FDA will make a decision about Ranbaxy's ANDA. Issuing that decision sooner rather than later has no effect on the confidentiality of the decision before the decision is made. Furthermore, the public interest is hardly served if FDA is permitted broad discretion to withhold for nearly nine years a decision on an ANDA that has the potential to hold up full generic competition in the marketplace indefinitely. Although Ranbaxy would like this Court to believe that, regardless of FDA's decision, Watson Pharmaceuticals Inc. will begin marketing in late November 2011, that atorvastatin product is not being manufactured by a generic competitor, but rather the brand company itself, and thus will not introduce *true* generic competition for LIPITOR®. Requiring FDA to issue, without further delay, a decision on Ranbaxy's exclusivity will permit more orderly preparations for generic entry to the marketplace, which can only benefit the public interest.

CONCLUSION

For the reasons stated herein, the Court should deny Defendants' Motions to Dismiss, and also for the additional reasons stated in Plaintiffs' Opening Memorandum, the Court should issue a Preliminary Injunction requiring FDA to issue a decision on whether or not Ranbaxy will be granted 180-day marketing exclusivity in connection with its atorvastatin ANDA.

Dated: April 11, 2011

Respectfully submitted,

MYLAN PHARMACEUTICALS INC. and
MATRIX LABORATORIES LTD.

By: /s/ Douglas B. Farquhar

Douglas B. Farquhar (D.C. Bar No. 386573)
Karla L. Palmer (D.C. Bar No. 444353)
Kurt R. Karst (D.C. Bar No. 482615)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2011, redacted copies of the foregoing Plaintiffs' Plaintiffs' Consolidated Reply Memorandum in Support of Plaintiffs' Motion for a Preliminary Injunction and Memorandum in Opposition to Defendants' Motions to Dismiss and the Supplemental Declaration of S. Wayne Talton Pursuant to 28 U.S.C. § 1746 (under seal in its entirety) were filed electronically using the CM/ECF system, causing notice to be sent to the following parties:

Gerald C. Kell
Senior Trial Counsel
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

Counsel for Defendant United States Food and Drug Administration

Carmen Shepard
Alexandra W. Miller
Carlos Angulo
Zuckerman Spaeder LLP
1800 M Street, N.W., Suite 1000
Washington, D.C. 20036-5802

Counsel for Intervenor-Defendant Ranbaxy Laboratories Limited

/s/ Douglas B. Farquhar
Douglas B. Farquhar
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329

Attorneys for Plaintiffs