IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS INC.,
781 Chestnut Ridge Road
Morgantown, West Virginia 26505

and

MATRIX LABORATORIES LTD.,
1-1-151/1, 4th Floor
Sai Ram Towers
Alexander Road
Secunderabad, India

Plaintiffs,

v.

UNITED STATES FOOD
AND DRUG ADMINISTRATION,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendant.

Case: 1:11-cv-00566
Assigned To : Roberts, Richard W.
Assign. Date : 3/18/2011
Description: General Civil

COMPLAINT

Plaintiffs Mylan Pharmaceuticals Inc. ("Mylan") and Matrix Laboratories Ltd. ("Matrix") (collectively, "Plaintiffs") for their Complaint in this matter aver and allege as follows:

Nature of Action

1. This action is brought to compel the United States Food and Drug Administration ("FDA") to decide issues relating to an Abbreviated New Drug

Application ("ANDA") submitted by Ranbaxy Laboratories Ltd. ("Ranbaxy") that threaten to arbitrarily, capriciously and unlawfully prevent or delay generic competition relating to LIPITOR® (atorvastatin calcium) tablets, which is the most widely prescribed drug in the United States with annual sales of more than $7 billion.

2. LIPITOR®, the brand name for the only approved version of atorvastatin calcium, has enjoyed 15 years of sales in the United States without generic competition, and is the most prescribed branded cholesterol-lowering medicine in the United States and in the world, according to its manufacturer. According to IMS Health Inc. ("IMS") prescription audit data, in the United States, annual sales of LIPITOR® exceeded $7.2 billion, and an estimated 2 billion doses of LIPITOR® were dispensed for the 12-month period ending in September 2010.

3. Upon market entry of generic LIPITOR®, it is estimated that United States consumers, the government, and third party payors could save between $10.9 million and $18.6 million per day, which equates to between $3.97 billion and $6.8 billion in potential savings per year. Federal payors alone (such as Medicare, Medicaid, and the Department of Veterans Affairs) could save between $1.3 billion and $2.3 billion in the first year after the launch of generic atorvastatin. Therefore, the earliest availability of more affordable, generic versions of LIPITOR® is significantly in the public interest.

4. Plaintiff Matrix is the sponsor of an ANDA for a generic version of LIPITOR®, which application has been pending at FDA for more than two years. Mylan

will distribute atorvastatin tablets manufactured by Matrix upon FDA's approval of its ANDA, which can be granted as early as June 28, 2011.[1]

5. In addition to Matrix, at least six other generic drug companies have submitted ANDAs to FDA for approval to market generic LIPITOR® products. Once approved, these applicants are also allowed to launch their generic versions of LIPITOR®. Such generic competition will drive down the average price paid by consumers, insurers, and government agencies, as discussed above.

6. However, FDA's actions (or inactions as they may be) are hindering Matrix's (and presumably other generic applicants') ability to lawfully prepare for the commercial launch of their lower-cost atorvastatin ANDA products to United States consumers at the earliest possible date. More specifically, FDA has arbitrarily, unreasonably, and unlawfully failed to decide whether the Agency will enforce the terms of its Application Integrity Policy ("AIP") against the atorvastatin ANDA application submitted by Ranbaxy, which on information and belief is the first generic applicant. Such a decision by FDA is particularly critical here because a decision in the affirmative on this issue would require FDA to consequently conclude, pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. § 301, *et. seq.*, and the AIP, that the Ranbaxy atorvastatin ANDA is not eligible for a period of 180-day marketing exclusivity. Such decision by FDA would also likely result in the approval of other

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[1] June 28, 2011 is the date of the expiration of pediatric exclusivity periods associated with certain patents for LIPITOR®, and thus the earliest possible date for FDA to approve and Plaintiffs to launch a generic atorvastatin tablet product.

pending ANDAs, and thus would permit generic competition and the marketing of lower cost generic LIPITOR® at the earliest possible date.

7. According to its own statements, Ranbaxy's atorvastatin ANDA (the "Ranbaxy ANDA") could be eligible for approval no earlier than November 2011, under the terms of a settlement agreement with the manufacturer of branded LIPITOR®. If Ranbaxy's atorvastatin ANDA is eligible for 180-day marketing exclusivity, then the market for generic atorvastatin will not be open to multiple other generic competitors, including Plaintiffs, until at least 180 days after Ranbaxy's first sale of its atorvastatin products, or May 2012.[2]

8. Upon information and belief, the AIP should be enforced against the Ranbaxy ANDA. As FDA has publicly stated, FDA found that Ranbaxy engaged in a pattern and practice of submitting to FDA drug applications containing false and unreliable data generated from Ranbaxy's Paonta Sahib, India manufacturing site, where, upon information and belief, Ranbaxy manufactures its generic LIPITOR®. FDA, however, has failed to decide whether it will actually enforce the AIP against the Ranbaxy ANDA, notwithstanding FDA's detailed findings.

9. As described more fully herein, if FDA enforces the AIP against the Ranbaxy ANDA, then the plain language of the FDC Act and the AIP require FDA to deny Ranbaxy's ANDA, and terminate any period of 180-day marketing exclusivity originally provided to Ranbaxy. This would permit other generic drug manufacturers to

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[2] On information and belief, Ranbaxy's ANDA has been pending at FDA for nearly nine years and has not received FDA approval (tentative or otherwise).

introduce generic versions of LIPITOR® as early as June 28, 2011, or in other words, at least 11 months earlier than currently anticipated.

10. Despite repeated requests, FDA has failed to decide, and disclose, whether the Agency will enforce the terms of the AIP against the Ranbaxy ANDA, and as a result, has failed to conclude that Ranbaxy is not eligible for a period of 180-day marketing exclusivity. FDA's indecision is permitting Ranbaxy to maintain a benefit to which it otherwise is not entitled, and further harming Plaintiffs and other atorvastatin ANDA holders whose ANDAs could be approved. Even worse, FDA's indecision is depriving millions of LIPITOR® patients access to lower-cost generic LIPITOR®.

11. FDA's decision about the Ranbaxy ANDA could open up the market, as early as June 28, 2011, to competition from Plaintiffs and other generic manufacturers with approved atorvastatin ANDAs. FDA's failure to make a decision, however, delays indefinitely the launch of generic atorvastatin, costing the public billions of dollars in savings, and costing generic manufacturers billions of dollars in lost sales. It further denies these manufacturers the ability to lawfully and appropriately plan for the commercial launch of generic LIPITOR® at the earliest possible date.

12. FDA's failure to decide, and disclose to Plaintiffs information that is critical to Plaintiffs' ability to launch a generic version of LIPITOR® at the earliest possible date will also cause Plaintiffs irreparable harm. For example, in order to prepare for a commercial launch, Plaintiffs must immediately begin implementing system-wide manufacturing plans. This requires the commitment and expenditure of millions of dollars, and the coordinated application of manufacturing capacity and human resources

so that Plaintiffs will be able to meet the unprecedented product demand as of the anticipated launch date. FDA's arbitrary and inexplicable failure to make a decision regarding the Ranbaxy ANDA places Plaintiffs' expenditures of human and financial capital, and adjustments of manufacturing strategy, at significant risk, which financial and other losses likely can never be recouped.

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.

14. As a result of FDA's inaction and failure to disclose whether FDA will deny any 180-day marketing exclusivity relevant to the Ranbaxy ANDA, Plaintiffs are suffering, and will continue to suffer, irreparable harm. That harm will continue if FDA fails to promptly decide, and provide information about, the status of the Ranbaxy ANDA, and, more importantly, the effect of that arbitrarily-withheld information on the status of Matrix's ANDA. Plaintiffs have exhausted any and all available administrative remedies, and/or any such further actions by Plaintiffs would be futile.

15. FDA's inaction and failure to disclose are unlawful, unreasonable, arbitrary and capricious. This action seeks redress for FDA's unlawful, unreasonable, arbitrary and capricious failure to decide, and disclose to the public, including Plaintiffs and other ANDA sponsors, critical information concerning FDA's review, approval, denial, and/or decision to grant a period of 180-day marketing exclusivity for the Ranbaxy ANDA.

Parties

16. Plaintiff Mylan is a corporation duly organized and existing under the laws of the State of West Virginia, with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505-4310.

17. Plaintiff Matrix is headquartered in India at 1-1-151/1, 4th Floor, Sai Tam Towers, Alexander Road, Secunderabad. Matrix is engaged in the manufacture of Active Pharmaceutical Ingredients ("APIs") and finished solid dosage oral forms. Matrix is the sponsor of an ANDA submitted to and pending with FDA for a generic version of LIPITOR® tablets. Mylan is the U.S. agent for Matrix for such purpose, and, following approval of the ANDA, will be the commercial distributor of the product.

18. Defendant FDA is an agency within the U.S. Department of Health and Human Services ("HHS"). HHS maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

Jurisdiction and Venue

19. This action arises under the FDC Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("Hatch-Waxman Amendments"), and the Medicare Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271); the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, 701-706; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202;

28 U.S.C. § 1361. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1361, and 1651.

20. This Court has personal jurisdiction over Defendant because it resides within this District.

21. Venue is proper in this District under 28 U.S.C. § 1391(e).

Facts Common To All Counts

Generic Drug Approval Process

22. The approval of generic drugs is governed by the FDC Act, as modified by the Hatch-Waxman Amendments and the MMA. *See* 21 U.S.C. § 355, *et. seq.*

23. Typically, generic drugs are sold at a lower price, resulting in cost savings to the public, including private insurers and the government (*i.e.*, through Medicaid and Medicare public payments).

24. The Hatch-Waxman Amendments permit generic drug manufacturers to obtain FDA approval of their products, so long as those products are shown to be bioequivalent to a Reference Listed Drug ("RLD") – usually a branded product that FDA has already approved as safe and effective. Generic drug manufacturers accomplish this by submitting ANDAs to FDA. *See id.* § 355(j).

25. An ANDA must contain a certification or statement with respect to each patent listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for the RLD. *See id.* § 355(j)(2)(A)(vii)-(viii). ANDA

sponsors may make one of four certifications[3] with respect to each such listed patent, only one of which is relevant in terms of market exclusivity – the so-called "Paragraph IV certification."

26. A Paragraph IV certification states that a listed patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See id.* § 355(j)(2)(A)(vii)(IV).

27. The Hatch-Waxman statutory scheme encourages generic drug companies to submit Paragraph IV certifications to clear the patent thicket. The first generic drug company to challenge a branded, Orange Book-listed patent by submitting a Paragraph IV certification usually encounters high research, development, and other costs in order to identify a legal challenge.

28. To encourage generic drug companies to bear the costs and/or risks associated with submitting a Paragraph IV certification, the FDC Act provides an incentive for the first applicant to do so. That first-to-file ANDA applicant receives an exclusive right to market generic versions of the brand-name drug product for a period of 180 days, which, during the time period relevant to the present action, is triggered by either the first commercial marketing of the generic drug or the date of a final court decision holding that the patent is invalid, not infringed, or unenforceable. *See id.* § 355(j)(5)(B)(iv)(I)-(II) (2002).

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[3] Alternatively, a sponsor may submit what is commonly referred to as a "section viii statement" pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) for patents claiming a method of using the RLD. This alternative type of submission is not at issue here.

29. The FDC Act and the Hatch-Waxman Amendments do not authorize FDA to confer 180-day marketing exclusivity with respect to an ANDA that contains, or is tainted by, unreliable or falsified data or information.

30. Specifically, under the plain language of the FDC Act, FDA is not authorized to approve an ANDA where: (a) "the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;" (b) "the application contains an untrue statement of material fact;" or (c) "the application does not meet any other requirement of [21 U.S.C. § 355(j)(2)(A)]." *Id.* at § 355(j)(4).

31. Further, the FDC Act requires an ANDA to contain, among other things, "information to show that the new drug is bioequivalent to the listed drug" and "the items specified in clauses (B) through (F) of subsection (b)(1)." *Id.* at § 355(j)(2)(A). The ANDA must also contain "a full statement of the composition of such drug" and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug." *Id.* at § 355(b)(1)(C)-(D); *see also* 21 C.F.R. §§ 314.50(d)(1), 314.94(a)(9).

32. In sum, if the ANDA does not contain reliable data and information, then FDA is expressly prohibited by statute from approving the ANDA. If FDA were to approve such an ANDA, that approval would be arbitrary, capricious, and contrary to law.

33. In furtherance of the statutory mandate prohibiting the approval of an ANDA that does not contain reliable data and information, FDA promulgated

Compliance Policy Guide Sec. 120.100 (7150.09), which sets forth FDA's AIP, 56 Fed. Reg. 46,191 (Sept. 10, 1991). Pursuant to the Compliance Policy Guide and the AIP, and consistent with the mandate set forth under the plain language of the FDC Act, an ANDA that does not contain reliable data and information cannot be cured with an amendment to the ANDA setting forth or substituting reliable data and information.

Matrix's ANDA

34. Matrix's ANDA No. 91-226 for atorvastatin calcium tablets, 10mg, 20mg, 40mg, and 80mg is pending at FDA. Mylan is the U.S. agent for this ANDA, and following its approval, will be the commercial distributor of the product. Recently, Mylan and Matrix settled patent litigation with Pfizer Inc. concerning its LIPITOR® drug product.

35. Subsequently, Mylan provided notice of the settlement to FDA. Accordingly, Matrix's ANDA should be eligible for final FDA approval as early as June 28, 2011. 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.

LIPITOR®

36. LIPITOR® is the most widely prescribed branded cholesterol-lowering medication worldwide, according to its manufacturer. LIPITOR® is also the most widely prescribed drug in the United States, with over 40 million prescriptions and with more than $7 billion in annual sales, much of which is reimbursed by federal healthcare programs, including Medicare and Medicaid.

37. According to government studies, consumers save billions of dollars each year by purchasing generic drugs, because generics typically enter the market at a lower price than brand-name drugs and quickly garner a significant share of the market. Increased generic competition is associated with additional lowering of drug prices. As FDA reports, "the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price." FDA, Generic Competition and Drug Prices (Mar. 1, 2010) *available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm.

38. As additional generic drug manufacturers obtain approval and launch their products, prices continue to fall. For products that attract a large number of generic drug manufacturers, as will the generic form of LIPITOR®, the average generic drug price falls to 20% of the branded drug price or lower. *Id.* Indeed, on information and belief, at least seven generic drug manufacturers, including Matrix, have submitted ANDAs for one or more dosage strengths of atorvastatin calcium tablets.

Ranbaxy's ANDA

39. Ranbaxy is a generic drug manufacturer with manufacturing locations throughout the world, including a location at Paonta Sahib, Simour District, Himachal Pradesch, India (the "Paonta Sahib site").

40. Upon information and belief, the Ranbaxy ANDA was the first ANDA submitted to FDA containing a Paragraph IV certification challenging patents listed in the Orange Book for LIPITOR®. As such, Ranbaxy's ANDA arguably qualified (at least at one time) for a period of 180-day marketing exclusivity.

41. The Ranbaxy ANDA was submitted to FDA prior to the December 8, 2003 enactment of the MMA, and contained a certification to an Orange Book-listed patent for LIPITOR®. Therefore, the triggering of Ranbaxy's 180-day marketing exclusivity is governed by the pre-MMA version of the statute. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II) (2002). If Ranbaxy's ANDA had been submitted after the effective date of the MMA, then other approval or marketing deadlines would have likely resulted in denial of Ranbaxy's ANDA, extinguishing any possible 180-day marketing exclusivity.

42. On or around February 25, 2009, FDA sent Ranbaxy a letter setting forth numerous allegations with respect to stability test results and other data generated from Ranbaxy's Paonta Sahib site, including but not limited to data relevant to several pending ANDAs. *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 ("February 2009 Letter") (attached hereto as Exhibit A).

43. In that same February 2009 Letter, FDA also invoked the AIP with respect to certain unidentified drug applications Ranbaxy submitted to FDA. *Id.*

44. The AIP states that defects in an ANDA submission, such as those identified in the February 2009 Letter, cannot be cured with an amendment to the ANDA setting forth or substituting untainted data.

45. The plain language of the FDC Act and the pronouncements set forth in the AIP require FDA to deny an implicated ANDA "regardless of whether the applicant attempts to replace the unreliable data with a new submission . . . ." (Exhibit A).

46. Upon information and belief, the Ranbaxy ANDA is one of the applications that is subject to the AIP. Therefore, Ranbaxy cannot "cure" any deficiencies with an amendment to that ANDA, but must submit a new ANDA for generic LIPITOR®. Under such circumstances, any 180-day marketing exclusivity for this product should be lost in view of the FDC Act and relevant FDA guidelines and policy.[4]

47. FDA has failed to decide, and disclose, whether any of Ranbaxy's applications submitted to FDA based on data generated from the Paonta Sahib site, including the Ranbaxy ANDA, will either be denied or will otherwise lose any claim to 180-day marketing exclusivity because they are tainted by unreliable data or other defects as set forth in the February 2009 Letter.

48. FDA's failure to decide, and disclose, critical information concerning the status of the Ranbaxy ANDA, including whether or not the Ranbaxy ANDA is the subject of the AIP that FDA invoked against Ranbaxy in February 2009, and whether any 180-day marketing exclusivity will thus be extinguished, directly affects Plaintiffs' rights, and directly affects whether Plaintiffs can launch a generic version of LIPITOR® as early as June 28, 2011. FDA has had ample time and opportunity to consider these issues.

49. FDA's failure to decide, and disclose to Plaintiffs information that is critical to Plaintiffs' ability to launch a generic version of LIPITOR® will cause Plaintiffs

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[4] Once it is determined that the Ranbaxy ANDA is not eligible for 180-day marketing exclusivity, no other LIPITOR® ANDA would be entitled to such exclusivity for the Orange Book-listed patents for which Ranbaxy submitted Paragraph IV certifications, and there would be no such exclusivity impeding approval of Matrix's atorvastatin ANDA or ANDAs of other generic drug manufacturers.

irreparable harm. Plaintiffs could obtain approval of the product as early as June 28, 2011, upon completion of FDA's regulatory review process. To adequately prepare to commercially launch generic LIPITOR® at that time, Matrix immediately needs to begin the manufacturing process for the product. For example:

(a) In order to begin the manufacturing process, validation batches of the product need to be prepared so that the commercial manufacturing process can be confirmed as producing a product with the correct properties and specifications. This validation process typically takes several months, and several validation batches need to be prepared for each of the four strengths of the product (10mg, 20mg, 40mg, and 80mg);

(b) Sufficient amounts of raw materials (APIs) and other materials are required to begin manufacturing the product on a commercial scale. In addition, sufficient amounts of other materials, such as excipients (inactive ingredients), bottles and packaging materials, must be acquired for commercial production; and

(c) In order for the manufacture and production schedule to proceed in a coordinated fashion, manufacturing capacity and human resources need to be appropriately allocated.

50. As the foregoing reflects, in order for Matrix to properly plan for a launch of generic LIPITOR® at the earliest possible date (as it statutorily should be permitted to do as early as June 28, 2011), Plaintiffs need to know immediately whether FDA will deny Ranbaxy 180-day marketing exclusivity in connection with the Ranbaxy ANDA, and therefore in connection with this product.

51. In the absence of such certainty, and if FDA only late in the game determines that no atorvastatin calcium ANDA sponsor will be granted 180-day marketing exclusivity, Plaintiffs will be irreparably harmed by, among other things, their inability to supply the market with its generic product at the earliest possible date, thus incurring a loss of revenue and goodwill from customers that cannot purchase sufficient amounts of generic LIPITOR®. Moreover, consumers will not be able to readily obtain a lower-priced, more-affordable generic alternative to LIPITOR®. Delaying, with no justification, the benefit of reduced pharmaceutical prices for the most prescribed product in the United States is clearly contrary to the public health and welfare.

52. If Matrix proceeds to manufacture generic LIPITOR® in anticipation of FDA properly applying the law, and then later learns that Ranbaxy's ANDA is unlawfully amended or approved and FDA grants 180-day marketing exclusivity, it will have wasted valuable resources manufacturing drug products that it will not be able to sell, as drug products have a limited shelf life. Matrix also will have needlessly adjusted its manufacturing and resource efforts away from other products, thereby causing significant financial and other harm.

53. Despite numerous requests (discussed below), FDA has failed to, and continues to refuse to, provide Plaintiffs with any indication or other information concerning whether Matrix's ANDA will be approvable as early as June 28, 2011, or if such approval will be delayed as a result of 180-day marketing exclusivity.

54. Given the substantial resources that must be committed in anticipation of FDA's approval of generic versions of LIPITOR®, and given FDA's failure to act,

Plaintiffs request that this Court require FDA to immediately determine the approval timeframe for Matrix's ANDA. Plaintiffs further request that this Court require FDA to determine, and provide information concerning, whether the Ranbaxy ANDA will be entitled to 180-day marketing exclusivity. Plaintiffs are legally entitled to such certainty, particularly in light of the circumstances described herein. *See* 5 U.S.C. § 706(1) (agency action must not be unlawfully withheld or unreasonably delayed).

55. On January 5, 2011, Mylan submitted a letter to FDA setting forth why Ranbaxy's ANDA for generic LIPITOR® could not serve as a basis for 180-day marketing exclusivity. FDA's position with respect to the Ranbaxy ANDA directly affects business decisions that must be made now. An orderly market cannot be established without an FDA decision well before June 28, 2011.

56. Mylan's January 5th Letter asserted, in view of the relevant statutory law and FDA policy, that FDA must disclose whether it will enforce the AIP against the Ranbaxy ANDA, that FDA must require Ranbaxy to submit a new ANDA reflecting untainted studies and other information, and that FDA must deny Ranbaxy 180-day marketing exclusivity for the Ranbaxy ANDA. Mylan's letter further asserted that FDA should determine that no company is entitled to 180-day marketing exclusivity if Ranbaxy's ANDA is tainted by the subject "pattern or practice" at the Paonta Sahib site and covered by the AIP as set forth in the February 2009 Letter.

57. On January 31, 2011, Mylan submitted a second letter to FDA repeating to FDA why the Agency must disclose whether the Ranbaxy ANDA has retained its first-to-file status and 180-day marketing exclusivity, despite FDA's invocation of the AIP.

58. After repeated requests for a meeting, Plaintiffs met in person with FDA officials on February 14, 2011, to communicate to FDA Mylan's position concerning the approval and launch preparation requirements and lead times of generic LIPITOR®, which position Mylan had previously set forth in its written correspondence with the Agency.

59. On February 22, 2011, Mylan submitted a third letter to FDA addressing why the FDC Act and FDA's regulations dictate that FDA must deny the Ranbaxy ANDA and any associated 180-day marketing exclusivity, why the available record demonstrates that the Ranbaxy ANDA cannot meet the statutory criteria for approval, and why FDA has ample authority to rule that the Ranbaxy ANDA is not entitled to 180-day marketing exclusivity. Mylan's letter further requested a decision from FDA by March 4, 2011, as to whether Ranbaxy has lost its 180-day exclusivity, and that, in the absence of an FDA decision, Plaintiffs will have no choice but to seek an expedited judicial resolution so that preparations can be made now for a launch of generic LIPITOR®.

60. Notwithstanding the February 14th meeting and Mylan's correspondence requesting a timely FDA decision, FDA has still failed to determine or to disclose whether the Ranbaxy ANDA has retained its first-to-file status, whether the Ranbaxy ANDA has 180-day marketing exclusivity, and whether the Ranbaxy ANDA is subject to the AIP.

61. FDA's failure to issue a decision or make a timely adjudication on legal and factual questions of 180-day marketing exclusivity that affect numerous applications

for generic LIPITOR®, including Matrix's ANDA, and that would permit reasonable judicial review and scrutiny, is arbitrary, capricious, unreasonable, and contrary to law.

62. If ANDA sponsors, including Plaintiffs, are kept in the dark about their rights, and if such sponsors, including Plaintiffs, have no effective recourse in the courts, then they will not make the investments necessary to mount patent challenges or make substantial investments necessary to build inventory and engage in lawful pre-market activities.

63. Such action or inaction by FDA with respect to pending LIPITOR® ANDAs, including Matrix's ANDA, is wholly contrary to the incentives that Congress contemplated when enacting the Hatch-Waxman Amendments.

64. Orderly markets, including the market for generic drugs, are critically dependent on FDA resolving issues of 180-day marketing exclusivity at the earliest possible moment and on allowing the courts time to exercise their appropriate role in reviewing agency action that is arbitrary, capricious, unreasonable and/or contrary to law. Such resolution is particularly important here in view of the pending AIP issues with respect to the Ranbaxy ANDA.

65. A ruling from this Court requiring FDA to immediately decide, and make public, the Agency's position with respect to the status of Ranbaxy's ANDA, and any associated 180-day exclusivity, is necessary and proper because there is an actual and justiciable controversy that is ripe for decision – namely, whether any ANDA sponsor, specifically Plaintiffs, is entitled to launch, at the earliest opportunity, a generic LIPITOR® product.

66. Given FDA's arbitrary, capricious, and unreasonable delay and refusal to address whether there is 180-day marketing exclusivity for generic LIPITOR®, and the irreparable injury that Plaintiffs will suffer in the absence of a timely disclosure by FDA, relief from this Court is necessary and appropriate.

Count I (Administrative Procedure Act - Delay)

67. The allegations in paragraphs 1-66 are incorporated herein by reference.

68. FDA's failure to make a public decision or other determination concerning whether the Ranbaxy ANDA contains unreliable data or information, or otherwise state whether FDA will enforce the AIP against the Ranbaxy ANDA, rendering the Ranbaxy ANDA ineligible for 180-day marketing exclusivity, is "agency action unlawfully withheld or unreasonably delayed," in violation of 5 U.S.C. §§ 706 and 701(b)(2).

69. FDA's delay and inaction are causing and will continue to cause irreparable harm to Plaintiffs. FDA's inaction is likely to improperly preclude Plaintiffs from entering the generic atorvastatin market for an indefinite period of time. Furthermore, requiring FDA to act will not cause any harm to FDA. FDA's indecision will cause Plaintiffs to suffer irreparable and significant economic harm, for which there is no legal redress.

70. FDA's indecision is depriving LIPITOR® patients access to a high-quality, affordable generic alternative, and is contrary to the public interest.

71. Therefore, Plaintiffs request this Court to issue an injunction requiring FDA to issue an immediate public decision concerning whether the Ranbaxy ANDA is eligible

for 180-day exclusivity, so that other generic drug manufacturers can prepare for launch of generic LIPITOR® products.

72. Plaintiffs also request that the Court issue a Declaratory Judgment that FDA's failure to make a public decision or other determination concerning whether the Ranbaxy ANDA contains unreliable data or information, or otherwise state whether FDA will enforce the AIP against the Ranbaxy ANDA, rendering the Ranbaxy ANDA ineligible for 180-day marketing exclusivity, is agency action unlawfully withheld or unreasonably delayed.

Count II (APA – Ranbaxy Exclusivity Period)

73. The allegations in paragraphs 1-72 are incorporated herein by reference.

74. FDA's failure to approve the Matrix ANDA on the basis of an exclusivity period for the Ranbaxy ANDA is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," in violation of 5 U.S.C. § 706, because FDA may not approve an ANDA if it contains inaccurate or false data. *See* 21 U.S.C. § 355(j)(4).

75. FDA's failure to approve the Matrix ANDA on the basis of an exclusivity period for the Ranbaxy ANDA is likely to improperly preclude Plaintiffs from entering the generic atorvastatin market for an indefinite period of time. FDA's indecision will cause Plaintiffs to suffer irreparable and significant economic harm, for which there is no legal redress.

76. FDA's failure to approve the Matrix ANDA on the basis of an exclusivity period for the Ranbaxy ANDA would deprive LIPITOR® patients access to a high-quality, affordable generic alternative, and is therefore contrary to the public interest.

77. Therefore, Plaintiffs request this Court to issue an injunction barring FDA from withholding or delaying final approval of Matrix's atorvastatin ANDA on the basis that Ranbaxy's 180-day marketing exclusivity blocks Matrix's atorvastatin ANDA from receiving approval.

78. Plaintiffs also request that the Court issue a Declaratory Judgment that a grant by FDA of a 180-day marketing exclusivity period to Ranbaxy on its atorvastatin ANDA would be arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of 5 U.S.C. § 706, because FDA may not approve an ANDA if it contains unreliable, inaccurate or false data. *See* 21 U.S.C. § 355(j)(4).

79. Furthermore, 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 by Ranbaxy's misconduct as set forth in FDA's February 2009 Letter. Such a denial equates to an FDA determination that any applicable 180-day marketing exclusivity period for generic LIPITOR® is extinguished.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Mylan and Matrix pray that this Court grant the following relief:

(a) Declare FDA's failure to make a public decision or other determination concerning whether the Ranbaxy ANDA contains unreliable data or information, or otherwise state whether it will enforce the AIP against the Ranbaxy ANDA, rendering it ineligible for 180-day marketing exclusivity,

is an agency action unlawfully withheld and/or unreasonably delayed, and is arbitrary, capricious, unreasonable and/or contrary to law;

(b) Declare that if any part of the Ranbaxy ANDA is tainted by Ranbaxy's misconduct as set forth in the February 2009 Letter, then FDA must immediately deny that ANDA, and determine that any applicable 180-day marketing exclusivity period for generic LIPITOR® is extinguished;

(c) Declare that there is no applicable period of 180-day marketing exclusivity for generic LIPITOR® at issue that will prevent FDA from approving Matrix's ANDA No. 91-226 as early as June 28, 2011, upon completion of FDA's regulatory review and approval process;

(d) Enjoin FDA from approving any ANDA for a generic version of LIPITOR®, if such ANDA contains unreliable data or information from the Paonta Sahib site;

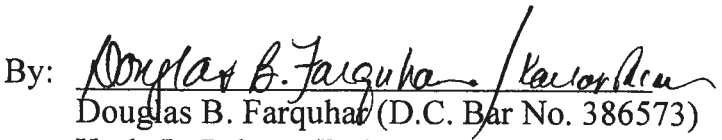
(e) Enjoin FDA from withholding final approval of Matrix's atorvastatin ANDA on the basis that Ranbaxy's 180-day marketing exclusivity blocks Matrix's atorvastatin ANDA from receiving approval; and

(f) Enter such other and further legal or equitable relief that it deems just and proper.

Dated: March 18, 2011

Respectfully submitted,

MYLAN PHARMACEUTICALS INC. and
MATRIX LABORATORIES LTD.

By: 

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Attorneys for Plaintiffs

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

February 25, 2009

Mr. Malvinder Mohan Singh
CEO & Managing Director
Ranbaxy Laboratories Limited
Corporate Office
Plot 90; Sector 32
Gurgaon - 122001 (Haryana)
India

Dear Mr. Singh:

The Center for Drug Evaluation and Research has determined that Ranbaxy Laboratories Limited (Ranbaxy) submitted untrue statements of material fact in abbreviated and new drug applications filed with the Agency. These findings concern the submission of information, such as from stability test results in support of pending and approved drug applications, from the Ranbaxy Laboratories Limited site located at Paonta Sahib, Sirmour District, Himachal Pradesh, India, (herein referred to as the "Paonta Sahib site"). The following are examples of the observations that support our conclusion that Ranbaxy submitted untrue statements of material fact in drug applications filed with the Agency:

1. Ranbaxy submitted stability information in numerous approved and pending applications that contain untrue statements of material fact, because Ranbaxy failed to include critical information about the storage and testing of the product. During a February 2006 inspection of the Paonta Sahib manufacturing facility, FDA found that hundreds of stability samples, many of which were being used for room temperature or accelerated stability studies, were being stored in refrigerators at approximately (b) (4) between the time they were removed from their stability chamber and the time they were tested. Among other things, FDA investigators found that the sample logbooks did not identify the samples that were being held in the refrigerators, their storage duration in the refrigerators, and the justification for this storage. FDA issued a June 15, 2006 warning letter to Ranbaxy based on its findings during this inspection, including the circumstances of these refrigerated stability samples.

2. Ranbaxy submitted an August 26, 2006 warning letter response that included corrections to the stability data previously submitted to the agency in several abbreviated new drug applications (ANDAs). The corrected stability test reports for Fluconazole Tablets, Ciprofloxacin Tablets, and (b) (4) show instances where stability test dates that previously had been submitted to the applications were false. In some cases stability testing was conducted several months later than the dates reported in the applications. Additionally, the firm reported stability test results for a given batch as occurring at the required accelerated or long term (e.g., 3, 6, 9, 12

month) time intervals, but actually conducted all of these tests on the same day, or within a period of days.

For Fluconazole Tablets and Ciprofloxacin Tablets, we found that even after Ranbaxy submitted its August 2006 warning letter response with the corrected stability test dates, the firm continued to submit the false stability test dates in annual report submissions to the respective applications.

These submissions of false information about the stability testing of the products were material to FDA's review of the applications.

3. In July 27, 2007 correspondence with the Division of Manufacturing and Product Quality, Ranbaxy's legal counsel, Kate C. Beardsley, provided the results of Ranbaxy's and (b) (4) stability verification project (hereafter referred to as "the verification report"). This report indicates that on February 22, 2006, Ranbaxy found 239 stability samples in the (b) (4) refrigerators which were being used to generate stability data for US drug applications.

   The verification report also included an August 22, 2006 listing of 67 stability samples for US filings that were held in the (b) (4) refrigerators. The listing shows that many of the stability samples were from exhibit batches and that, based on Ranbaxy's estimates, the samples were held in the (b) (4) refrigerators between 2 days and 201 days. The report also indicates that the time held in the refrigerator is estimated because documentation was not available which clearly shows the length of time the samples were held in the refrigerators.

   This unusual storage condition for stability testing was not defined in the submitted protocol for U.S. drug applications, and prior to the February 2006 inspection, was not reported to FDA. The stability protocols and stability data submitted in Ranbaxy's filings specify the use of controlled room temperature storage of stability samples at (b) (4) and (b) (4) relative humidity (RH) or storage of stability samples for accelerated studies at (b) (4) and (b) (4) RH. Thus, these protocols and stability data submitted by Ranbaxy to the applications, which failed to describe the refrigeration of stability samples, were false. These submissions of false information about the stability of the products were material to FDA's review of the applications.

4. The July 27, 2007 correspondence includes the results of Ranbaxy's verification audit of its stability data associated with the samples held in the (b) (4) refrigerator. The verification report indicates that numerous discrepancies were found in the data, as follows:

   - 129 stability samples (comprising 171 stability test reports) which were on stability were verified from a list of 239 samples for U.S. filings in the (b) (4)

refrigerator. (According to the verification report, the remaining stability samples were for discontinued stability studies.)

- All of the 129 samples were analyzed for all stability stations required by the respective protocol and all results were found to be within specifications.

- Dates of analysis for these 129 samples needed correction in all 171 stability test reports.

- In thirteen instances there was an incorrect estimate of the number of days that the stability samples were held at (b)(4) (Apparently, these instances were found in internal stability reports.)

- There were 122 instances of stability reports having incorrect values for test results (i.e., incorrectly transcribed from raw data).

- The package type was incorrectly reported in one stability report.

The verification report includes copies of updated stability test reports with numerous corrections in the stability data. These submissions of false information about the stability testing of the products were material to FDA's review of the applications.

5. The July 27, 2007 correspondence also includes the results of Ranbaxy's verification audit of the stability data filed with the Agency for approval of (b)(4) pending ANDAs; and audits of the stability data filed in 15 approved ANDAs. The audit results included the following findings:

    - Audit of the stability data in (b)(4) pending ANDAs found 2257 errors in entries for the dates of analysis; and errors in 1385 entries for stability test results, and tests for which corrections were made in specification limits.

    - Audit of the stability data filed in 15 approved ANDAs selected for the audit found a combined total of 1676 errors, which include errors in entries for the dates of analyses, packaging and errors in stability test results.

    These submissions of false information about the stability testing of the product were material to FDA's review of these applications.

6. Our review of certain stability reports that were corrected by Ranbaxy based on audits conducted during its verification project, and which were submitted as corrected to the Agency in the July 27, 2007 correspondence from Ms. Beardsley, and in subsequent filings to the affected drug applications, revealed the following:

- The corrected stability test reports show that in numerous instances stability testing actually was conducted several weeks or months later than the dates that originally were reported in the drug applications or annual reports. Additionally, the corrected data shows that in many instances the stability test results reported at different time intervals, (e.g., 3, 6, and 9 months) actually were conducted on the same day or within a few days of each other.

- Simvastatin Tablets are included in Ranbaxy's listing of stability samples for U.S. filings that were held in the (b)(4) refrigerators, and Simvastatin Tablet stability reports that were corrected by Ranbaxy based on its verification audit are included in Ms. Beardsley's July 27, 2007 correspondence with Mr. Campbell.

  We observed several differences between the corrected stability reports included in the July 27, 2007 correspondence, and other corrected stability reports for the same batches that were included with Ranbaxy's November 1, 2007 annual report submission to Ohm Laboratories ANDA 76-285, Simvastatin Tablets. Both sets of corrected stability reports show that they were prepared, checked and approved by three individuals of your firm.

  For the batches that were identified in the listing of stability samples held in the (b)(4) refrigerators, the corresponding corrected stability reports included with the July 27, 2007 correspondence note that controlled room temperature samples were kept at (b)(4) for varying periods up to 116 days before completion of analysis. In contrast, the corrected stability reports that were submitted to the Office of Generic Drugs with the November 1, 2007 annual report lack any reference to the storage of Simvastatin stability samples at (b)(4) There also are instances where for the same batches, the stability test dates and test results differ between the two submissions of corrected stability reports.

- Corrected stability reports were included in Ranbaxy's June 18, 2007 and September 14, 2007 amendments to pending NDA (b)(4) . The June 18, 2007 amendment states that none of the changes made to correct the originally submitted stability data affect previous conclusions about the product's stability; yet the amendment also states that based on the 18 month stability data, Ranbaxy is withdrawing the (b)(4) package configuration. In fact, the corrected data shows that a specified impurity in one batch exceeded the specification limits at the (b)(4) month test interval. This test result would have affected the conclusion about the product's stability at the (b)(4) month test interval had the firm not withdrawn the (b)(4) package configuration.

  The September 14, 2007 amendment includes both the uncorrected and corrected stability data, and shows that prior to the verification project the original stability data submitted for approval of the (b)(4) package configuration erroneously

reported a passing result for the same specified impurity at the (b)(4) month stability test interval.

All of the above examples of the submission of false information were material to the review of the applications.

7. During a March 2008 preapproval inspection for pending ANDA (b)(4), at Batamandi (Unit II) in the Paonta Sahib site, it was found that exhibit batch records previously submitted for FDA approval of the pending ANDA contained the signatures or initials of Ranbaxy employees who were not present in the facility on the dates documented in the batch records. The employees' signatures or initials appeared in blocks documenting the performance and verification of certain manufacturing steps. This observation also is the subject of the FDA Warning Letter issued to your firm on September 16, 2008. The submission of this false information was material to the review of the application. Your firm withdrew its pending ANDAs (b)(4); and (b)(4); both of which listed Batamandi as the manufacturing site.

These and other findings indicate a pattern and practice of submitting untrue statements of material fact and other wrongful conduct, which raise significant questions regarding the reliability of the data and information contained in applications (pending and approved) that your firm has filed with the Agency and which contain data developed at the Ranbaxy Laboratories, Paonta Sahib site.

In accordance with FDA policy, the Agency will assess the validity of the data and information in all of Ranbaxy's affected applications which contain data developed at the Paonta Sahib site. This assessment, which is ongoing, is a part of the review of these applications, and thus will take priority over substantive scientific data review until questions of data integrity are resolved. This means that the Agency does not intend ordinarily to conduct or to continue its normal substantive scientific review (including review of data and labeling) of any such pending application or supplement, or of any new application or supplemental applications filed after the date of this letter, that contain data developed at the Paonta Sahib site, during a validity assessment of that application.

In the case of certain applications, however, the Agency may review and act on an application prior to completion of the validity assessment in special circumstances where such an action is clearly in the interest of public health.

The Agency's policies regarding validity assessments and corrective actions that companies may take are described more fully in the Agency's policy entitled "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities, Final Policy" which was published in the Federal Register of Tuesday, September 10, 1991. This Policy states in part:

> When FDA finds, based on fraudulent data in an application, that the data in the application are unreliable, the agency intends ordinarily to exercise its authority, under applicable statutes and regulations, to refuse to approve the application (in the case of a pending application) or to proceed to withdraw approval (in the case of an approved application), regardless of whether the applicant attempts to replace the unreliable data with a new submission in the form of an amendment or supplement. Thus, if the applicant wishes to replace the false data with a new submission, the new submission should be in the form of a new application. The new application should identify the parts of the original application that were found to be false. The truthfulness and accuracy of the new application should be certified by the president, chief executive officer, or other official most responsible for the applicant's operations.

Guidance for firms (regarding audits) and the Agency in conducting validity assessments also is contained in a document entitled "Points to Consider for Internal Reviews and Corrective Action Operating Plans" the availability of which was announced in the same issue of the Federal Register.

These documents can be obtained at the following web addresses:

> http://www.fda.gov/ora/compliance_ref/frn/fraud_ill_grat.html and
> http://www.fda.gov/ora/compliance_ref/aip_points.html

If you intend to cooperate with the Agency to attempt to resolve the questions of data integrity and reliability, and/or you wish to discuss the Agency's finding that a validity assessment is warranted, you should arrange a meeting with Mr. Richard L. Friedman, Director, Division of Manufacturing and Product Quality. He can be reached at the following address and telephone number:

Mr. Richard L. Friedman, Director
Division of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 4224
Silver Spring, Maryland 20993
Phone: (301) 796-3267

If you do not intend to address the question of validity with regard to a pending or approved application which contains data developed at the Paonta Sahib site, you may withdraw the application pursuant to 21 CFR 314.150(d). Enclosed is a listing of all Ranbaxy's applications that are currently approved, pending, or for which a not-approvable letter has been issued. Please confirm your agreement with this listing and

inform the Agency of the action you intend to take with regard to each of the applications within ten days of the date of issuance of this letter.

Although the Agency's policy, "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities, Final Policy" is being applied only to pending and approved applications which contain data developed at the Paonta Sahib site, we note that it is your firm's responsibility to ensure the accuracy and reliability of all submissions to the Agency.

Sincerely,

Janet Woodcock, M.D.,
Director,
Center for Drug Evaluation and Research

Enclosure

Cc: Ms. Kate C. Beardsley
Buc & Beardsley
Suite 600
919 Eighteenth Street, N.W.
Washington, D.C. 20006-5503

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 2, 2009

Mr. Malvinder Mohan Singh
CEO & Managing Director
Ranbaxy Laboratories Limited
Corporate Office
Plot 90; Sector 32
Gurgaon – 12201 (Haryana)
India

RE: February 25, 2009 letter from FDA to Ranbaxy

Dear Mr. Singh:

I am writing concerning the Agency's letter to you of February 25, 2009. That letter noted that Ranbaxy's legal counsel, Kate C. Beardsley, transmitted to FDA, by correspondence dated July 27, 2007, audit reports from the stability verification project that was conducted by Ranbaxy and a hired consultant. We understand that some individuals may have read the agency's February 25, 2009 letter to suggest that Ms. Beardsley and/or her firm were responsible for generating the information that was submitted to FDA. No such suggestion was intended. Our current understanding is that Ms. Beardsley and her firm only transmitted those audit reports to FDA. We hope this clears up any confusion. Thank you.

Sincerely,

/S/

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Cc: Ms. Kate C. Beardsley, Esq.