IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES LIMITED
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad - 500 034, Andhra Pradesh
India,

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

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, Maryland 20993,

KATHLEEN SEBELIUS,
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201, and

MARGARET HAMBURG, M.D.,
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, Maryland 20993,

Defendants.

Civil Action No.

COMPLAINT

Plaintiffs Mylan Laboratories Limited ("Mylan Labs") and Mylan Pharmaceuticals Inc. ("Mylan Pharms") (collectively, "Mylan"), for their Complaint against the United States Food and Drug Administration; Kathleen Sebelius, in her official capacity as the Secretary of Health and Human Services; and Margaret Hamburg, M.D., in her official capacity as the Commissioner of the United States Food and Drug Administration (collectively, "FDA"), allege the following:

Nature Of The Action

1. This is an action for declaratory and injunctive relief arising out of FDA's arbitrary, capricious, and unlawful decision to grant so-called "180-day exclusivity" to another company in connection with Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, coupled with FDA's unlawful refusal to grant final approval of Mylan's application to market its own competing generic Valsartan Tablets. Mylan is entitled to, *inter alia*, immediate declaratory and injunctive relief:

(a) Declaring that FDA's decision to grant 180-day exclusivity to another generic applicant, and to deny Mylan final approval on the basis of such exclusivity, is arbitrary, capricious, an abuse of discretion, and contrary to law, because any such eligibility for exclusivity has been forfeited as a matter of law;

(b) Setting aside and vacating FDA's decision granting exclusivity (and refusing to approve Mylan's application), and declaring that any 180-day exclusivity for Valsartan Tablets has been forfeited;

(c) Enjoining FDA from awarding 180-day exclusivity for Valsartan Tablets; and

(d) Directing FDA to grant Mylan immediate final approval.

2. Mylan Labs is the holder of an abbreviated new drug application ("ANDA") containing a so-called "paragraph IV certification" for a generic version of Valsartan Tablets 40 mg, 80 mg, 160 mg, and 320 mg—a prescription drug approved for the treatment of certain cardiovascular diseases and currently marketed by Novartis Pharmaceuticals Corp. ("Novartis") under the brand-name Diovan®. Mylan Labs duly and diligently advanced its application before the FDA, and Mylan expected that the Agency would grant final approval of that application upon the expiration of relevant Orange Book-listed patents (and the associated period of pediatric exclusivity) on September 21, 2012.

3. Although another generic manufacturer is the so-called "first applicant" under the controlling statute (and thus was *eligible* for 180-day exclusivity), that company has forfeited any eligibility for 180-day generic marketing exclusivity, clearing the way for immediate final approval of Mylan's application. FDA therefore must immediately approve Mylan's ANDA for generic Valsartan Tablets, 40 mg, 80 mg, 160 mg, and 320 mg.

4. Despite Mylan's repeated written requests, FDA nevertheless refused to grant Mylan final approval, or otherwise find that the "first applicant" has forfeited its exclusivity under the applicable statute. Such final agency action is arbitrary, capricious, an abuse of discretion, and contrary to law, in violation of both the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Administrative Procedure Act ("APA").

5. To prevent significant harm to Mylan and the public—harm that grows each day that Mylan is unlawfully kept off of the market—Mylan is entitled to, *inter alia*, declaratory and injunctive relief from this Court declaring that any exclusivity has been forfeited, enjoining FDA from awarding such exclusivity, and ordering FDA to immediately grant final approval of Mylan's ANDA No. 90-886 for Valsartan Tablets, 40 mg, 80 mg, 160 mg, and 320 mg.

Parties

6. Plaintiff Mylan Laboratories Limited is a company organized and existing under the laws of India, with a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills Hyderabad - 500 034, Andhra Pradesh, India.

7. Plaintiff Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan is engaged in the research, development, manufacture and distribution of quality generic pharmaceutical products.

8. Defendant Kathleen Sebelius is the Secretary of Health and Human Services ("HHS"), and the official charged by law with administering the FFDCA. She is sued in her official capacity. Secretary Sebelius maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

9. Defendant Margaret Hamburg, M.D. is the Commissioner and senior official of FDA. Commissioner Hamburg has been delegated the authority to administer the drug approval provisions of the FFDCA through FDA. She is sued in her official capacity. She maintains offices at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

10. Defendant FDA is an agency within the Public Health Service and is a part of HHS. FDA maintains offices at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

Jurisdiction and Venue

11. This action arises under the FFDCA, 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") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(b)(1), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("MMA"); the APA, 5 U.S.C. § 551 *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1361.

12. This Court has personal jurisdiction over the federal Defendants because they are either located in, and/or conduct substantial business in, and/or have regular and systematic contact with, this District. Venue is proper in this District under 28 U.S.C. § 1391(e).

13. FDA's final agency action constitutes an actual controversy for which Mylan is entitled to review and relief under 5 U.S.C. §§ 702, 704-706. Mylan has standing to maintain this action, pursuant to the APA, as a legal entity that has been adversely affected by final agency action.

14. There exists an actual, substantial, and continuing controversy between the parties regarding FDA's application of the FFDCA, and in particular the MMA's exclusivity forfeiture provisions. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201, 2202.

Background

I. Statutory Framework For Approval Of New And Generic Drugs.

A. New Drugs—NDAs And Patent Listing Requirements.

15. A company seeking to sell an original, new drug must file a new drug application ("NDA") containing technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling for use of the drug for which approval is requested. *See* 21 U.S.C. § 355(b)(1).

16. An NDA applicant also must submit information to FDA with respect to any patent that the applicant asserts "claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). After approving the NDA, FDA publishes this patent information in the Patent and Exclusivity Information Addendum to its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See id.*; 21 C.F.R. § 314.53(e).

B. Generic Drugs—ANDAs And Patent Certifications.

17. A company seeking FDA approval to market a generic version of a previously-approved NDA drug may file an ANDA without repeating the comprehensive and extensive human clinical studies conducted for the NDA drug. A generic ANDA applicant must, however, establish that its proposed product is bioequivalent to the already-approved NDA drug and, with certain exceptions, that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling as the approved NDA drug. *See* 21 U.S.C. § 355(j)(2)(A).

18. An ANDA also must include one of four certifications with respect to each patent properly listed in the Orange Book for the NDA drug: (I) that there is no patent information; (II) that the listed patent has expired; (III) that the ANDA applicant will not market its generic drug until after the expiration of the listed patent, a so-called "paragraph III certification;" or (IV) that the listed patent is invalid, unenforceable and/or will not be infringed by the proposed generic drug, a so-called "paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii).

19. With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug before expiration of the Orange Book-listed patent must submit a paragraph IV certification. Submitting a paragraph IV certification has two important consequences.

20. First, submitting a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), thereby vesting the district courts with subject matter jurisdiction to adjudicate whether the proposed generic drug infringes the subject patent before the drug has actually been marketed.

21. Second, the first applicant to submit an ANDA for a drug product containing a paragraph IV certification for any listed patent may be eligible to market its generic product free

from generic competition for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This statutory period of marketing exclusivity is commonly known as the "180-day exclusivity" period.

C. 180-Day Exclusivity.

22. In instances where a company lawfully is entitled to generic exclusivity, the provision operates by preventing FDA from approving subsequent generic competitors during the exclusivity period:

> (iv) ***180-DAY EXCLUSIVITY PERIOD***-
>
> (I) EFFECTIVENESS OF APPLICATION – Subject to subparagraph (D), if the application contains a [paragraph IV certification] . . . and is for a drug for which a ***first applicant*** has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv) (emphasis added). The statute defines "180-day exclusivity period" and "first applicant" as follows:

> (aa) ***180-DAY EXCLUSIVITY PERIOD*** – The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.
>
> (bb) ***FIRST APPLICANT*** – As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a [paragraph IV certification] . . . is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [paragraph IV certification] . . . for the drug.

21 U.S.C. § 355(j)(5)(B)(iv)(II) (emphasis added).

23. The statute therefore creates the opportunity for the "first applicant" to file a paragraph IV ANDA to enjoy, *under certain limited situations*, a 180-day period free from other generic competition, provided only that certain other statutory requirements are met.

24. One such requirement is to avoid a so-called "forfeiture event." That is, the 180-day exclusivity period can be "forfeited" if a so-called "forfeiture event" occurs. *See* 21 U.S.C.

§§ 355(j)(5)(D)(i) and (ii). Congress enacted these forfeiture events 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.'" *Hi-Tech Pharmacal Co. Inc. v. FDA et al.*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) (quoting 149 CONG. REC. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer)).

25. Relevant here, a forfeiture event occurs if "***[t]he first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed***, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." 21 U.S.C. § 355(j)(5)(D)(i)(IV) (emphasis added). This provision operates to ensure that first applicants diligently and actively pursue final approval of their ANDAs at all times, and do not simply "park" their ANDAs, thereby blocking lawful generic entry by others indefinitely.

26. Thus, Congress intentionally acted to ensure that a first applicant that fails to obtain timely tentative approval will forfeit its eligibility for exclusivity where there has been neither a change in, nor a review of, the requirements for approval that caused the first applicant's failure to obtain tentative approval within the statutory timeframe. By enacting the tentative approval forfeiture provision, Congress altered the incentive structure to ensure that only diligent first applicants were eligible for 180-day exclusivity.

27. FDA "may not . . . change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) (quoting *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994)).

28. According to FDA, the TA forfeiture provision "establishes a ***bright-line rule***":

> Under this provision, it is not sufficient to show that FDA changed or reviewed the requirements for approval while the application was under review. The applicant must also show that its failure to obtain tentative approval at the 30 month date is caused by this change in or review of approval requirements—that is, *the issues holding up approval at the 30 month date must be causally connected to the approval requirements that FDA reviewed or changed.*

(Mar. 1, 2012 Ltr. from J. Woodcock to C. Klein, Docket No. FDA-2011-P-0486, at 4) (emphasis added).

29. According to FDA, the statute requires, and expressly imposes an obligation on, the Agency to make a detailed and reasoned finding that a change or review has occurred, and that such change or review directly caused the failure to meet the 30-month deadline (*i.e.*, in FDA's own words, "*the issues holding up approval at the 30 month date must be causally connected to the approval requirements that FDA reviewed or changed*"), before finding that the exception applies. (*See id.*)

30. Further, to comply with the need for transparency under the statute and the APA, FDA also must make the detailed and reasoned basis for its decision both timely and publicly known before it allows a first applicant to bypass Congress' 30-month deadline in order to allow for meaningful judicial review. Indeed, failing to either timely or publicly disclose the reasoned basis for its decision to permit a first applicant to bypass Congress' 30-month deadline in order to allow for meaningful review runs afoul of not only Hatch-Waxman and the APA, but also the right of the judicial system to fulfill its obligation to review agency action brought for review.

II. Factual Background.

A. The Reference Listed Drug: Diovan® (Valsartan) Tablets.

31. The reference listed, or brand-name, drug for Mylan's Valsartan Tablet ANDA is Novartis' prescription cardiovascular medication, Diovan® Tablets, 40 mg, 80 mg, 160 mg, and 320 mg, approved under NDA No. 21-283, and known generically as Valsartan Tablets.

32. Novartis submitted information to FDA on several patents for listing in the Orange Book in connection with Diovan® Tablets, including U.S. Patent Nos. 5,399,578 ("the '578 patent"); 5,972,990 ("the '990 patent"); and 6,294,197 ("the '197 patent"). FDA subsequently listed the '578, '990 and '197 patents in the Orange Book in connection with Diovan® and NDA No. 21-283, and has not de-listed or withdrawn any of these patents.

B. FDA Receives The First Paragraph IV ANDA For Valsartan Tablets And The First Applicant Fails To Secure Tentative Approval Within 30 Months.

33. On information and belief, FDA received the first paragraph IV ANDA referencing Novartis' Diovan® Tablets on December 28, 2004.

34. On information and belief, Ranbaxy filed ANDA No. 77-492 on December 28, 2004, seeking approval to market Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, prior to the expiration of one or more patents listed in the Orange Book in connection with Novartis' Diovan® products. Thus, on information and belief, Ranbaxy submitted the first ANDA for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, that included a paragraph IV certification to one or more of the listed '578, '990 and '197 patents.

35. On information and belief, Ranbaxy's ANDA contains a paragraph III certification to the '578 patent, mandating that Ranbaxy's Valsartan Tablet ANDA was not eligible for final approval until the expiration of the '578 patent and its associated pediatric exclusivity on September 21, 2012.

36. On information and belief, Ranbaxy is the "first applicant" to submit a Paragraph IV ANDA for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, and was provisionally *eligible* for 180-day generic marketing exclusivity for these products. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I).

37. In order to maintain its eligibility for 180-day exclusivity, however, Ranbaxy was statutorily required to receive tentative approval for its Valsartan Tablet ANDA within 30 months of ANDA submission, or by June 28, 2007, at the latest. 21 U.S.C. § 355(j)(5)(D)(i)(IV).

38. On information and belief, Ranbaxy failed to obtain tentative approval of its ANDA No. 77-492 for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, within the 30-month period required by the relevant portions of the FFDCA.

39. On information and belief, Ranbaxy's ANDA No. 77-492 did not receive tentative approval, and was otherwise not eligible for tentative approval, prior to June 28, 2007. Instead, Ranbaxy received tentative approval on October 25, 2007, *some four months after the 30-month tentative approval deadline*. FDA did not make Ranbaxy's tentative approval letter publicly available at that time.

C. Mylan Submits A Paragraph IV ANDA For Valsartan Tablets.

40. On September 15, 2008, after Ranbaxy had failed to secure tentative approval within 30 months, Mylan submitted ANDA No. 90-866 for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg.

41. Mylan's ANDA contains a paragraph III certification to the '578 patent, indicating that Mylan did not seek final approval prior to the expiration of such patent, and a paragraph IV certification to the listed '197 patent.

42. As a result of Mylan's paragraph III certification to the '578 patent, like Ranbaxy, Mylan's Valsartan Tablet ANDA was not eligible for final approval until the expiration of the '578 patent and its associated pediatric exclusivity on September 21, 2012.

D. Mylan Seeks Final Approval Of Its Valsartan Tablet ANDA, And Repeatedly Requests Information Regarding FDA's Forfeiture Determination.

43. By letter dated July 24, 2012, Mylan wrote to FDA seeking final approval of its Valsartan Tablet ANDA immediately upon expiration of the '578 patent's pediatric exclusivity period, on the basis that Ranbaxy has forfeited its exclusivity for all strengths of Valsartan Tablets for failure to obtain tentative approval within the statutory deadline. FDA did not respond to Mylan's July 24, 2012, correspondence.

44. In connection with Mylan's July 24, 2012, final approval request, Mylan reviewed the FDA review history of, and approval requirements for, Mylan's Valsartan Tablet ANDA, and Mylan did not discover any changes in or review of the approval requirements that would qualify as the forfeiture exception under 21 U.S.C. § 355(j)(5)(D)(i)(IV).

45. Moreover, Mylan also reviewed the publicly available review documentation and FDA correspondence for the reference listed drug, Novartis' Diovan® Tablets, and Mylan did not discover anything that, based on Mylan's experience, would have caused or indicated the presence of any changes in or review of the requirements for FDA approval of ANDAs referencing Diovan®, or anything else that would have directly caused Ranbaxy to fail to meet the statutory deadline, that would satisfy the forfeiture exception under 21 U.S.C. § 355(j)(5)(D)(i)(IV).

46. Based on Mylan's review, on information and belief, there was no change in, or review of, the requirements for FDA approval of Valsartan Tablet ANDAs that would have prevented FDA from awarding tentative approval to Ranbaxy's Valsartan Tablet ANDA prior to

the 30-month forfeiture deadline. Mylan indicated as much to FDA in its July 24, 2012, correspondence.

47. Again, in August 2012, Mylan requested final approval of its Valsartan Tablet ANDA upon expiration of the '578 patent's associated pediatric exclusivity on September 21, 2012. On August 10, 2012, Mylan submitted a Labeling Amendment to its Valsartan Tablet ANDA, effecting minor changes to conform its product labeling to follow recent changes made to the Diovan® labeling. Then, on August 16, 2012, Mylan submitted another Labeling Amendment to its Valsartan Tablet ANDA responding to FDA's labeling comments from the day prior, and again effecting minor changes to conform its labeling to follow that of Diovan®.

48. In both of Mylan's August 2012 Labeling Amendments, Mylan referenced its July 24, 2012, request for final approval. Mylan's final Labeling Amendment, dated August 16, 2012, also explicitly requested final approval as described in Mylan's July 24th correspondence. FDA did not respond to Mylan's repeated requests for final approval.

49. In early September 2012, Mylan representatives directly contacted FDA personnel seeking information as to FDA's 180-day exclusivity forfeiture decision for Valsartan Tablets, referencing Mylan's July 24th correspondence and request for final approval. FDA did not provide any substantive information about its exclusivity determination for, or approval status of, Valsartan Tablet ANDAs.

50. On September 17, 2012, Mylan submitted additional correspondence to FDA, again seeking final approval of its ANDA No. 90-866 immediately upon expiration of the pediatric exclusivity period associated with the '578 patent. Mylan's September 17, 2012, correspondence also again requested a formal agency determination that Ranbaxy had forfeited its 180-day exclusivity for failure to secure tentative approval within the 30-month statutory

deadline. Mylan also requested that FDA immediately and specifically identify any purportedly relevant change in or review of the approval requirements underlying Ranbaxy's failure to obtain tentative approval, in the event that FDA applied such a forfeiture exception and determined that Ranbaxy did not forfeit its exclusivity.

51. Prior to September 21, 2012, FDA did not respond to Mylan's repeated requests for final approval, and also did not respond to Mylan's requests for information regarding Ranbaxy's apparent forfeiture of its 180-day exclusivity for failure to obtain tentative approval of its Valsartan Tablet ANDA prior to the 30-month statutory deadline.

52. On September 21, 2012, FDA, for the first time, made Ranbaxy's October 25, 2007 tentative approval letter (hereinafter the "October 25, 2007, Tentative Approval Letter") publicly available by posting a copy of the letter on the Agency's Drugs@FDA website. FDA noted in that letter that the Agency was not addressing issues relating to Ranbaxy's eligibility for 180-day exclusivity, except to observe that there had been a "change" to the USP monograph for Valsartan,[1] published on May 1, 2007, and that the Agency considered that monograph change to be a change in the requirements for approval imposed after the date on which Ranbaxy's ANDA was filed. The October 25, 2007, Tentative Approval Letter did not provide any explanation for why the cited monograph update was considered a "change" in the approval requirements, or how that purported "change" could have "caused" any delay in Ranbaxy's tentative approval.

53. Later that same day (September 21st), Mylan submitted additional correspondence to FDA and repeated its request for immediate final approval on the ground that any eligibility for exclusivity has been forfeited.

[1] The USP (or United States Pharmacopeia) is a scientific nonprofit organization that, *inter alia*, sets—and publishes a compendium of—drug standards (or monographs) for the identity, strength, quality, and purity of medicines, including active drug substances and finished dosage forms.

E. FDA Tentatively Approves Mylan's ANDA, And Refuses To Finally Approve That Application Based Upon FDA's Unlawful Determination That Ranbaxy Is Entitled To 180-Day Exclusivity.

54. In a letter dated Friday, September 28, 2012, FDA granted tentative approval to Mylan's ANDA No. 90-866 for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg.

55. FDA's September 28, 2012, tentative approval letter to Mylan states, *inter alia*:

> We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, *we are unable to grant final approval to your ANDA at this time because of the exclusivity issue noted below*. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacturing and testing of the drug product).

(Sept. 28, 2012 Tentative Approval Ltr. for Mylan's Valsartan Tablets at 1 (bold in original; emphasis added)).

56. According to FDA's September 28, 2012, tentative approval letter to Mylan, FDA refused to grant final approval to Mylan's ANDA solely because the Agency determined that another applicant is entitled to 180-day generic exclusivity:

> [W]e are unable at this time to grant final approval to your ANDA because another applicant submitted an ANDA for Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg, containing a paragraph IV certification prior to the receipt of your ANDA. This other ANDA, therefore, is eligible for 180-day generic drug exclusivity for Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg. Your ANDA will be eligible for final approval upon the expiration of the other applicant's 180-day exclusivity identified in section 505(j)(5)(B)(iv) of the Act, or that exclusivity is otherwise resolved.

(*Id.* at 2).

57. FDA's tentative approval letter to Mylan does not identify the change in or review of approval requirements upon which the Agency relied for purposes of determining that the first

applicant has not forfeited 180-day exclusivity. Indeed, FDA's tentative approval letter does not even acknowledge that the first applicant failed to obtain tentative approval by the 30-month statutory deadline.

58. FDA's tentative approval letter to Mylan does not provide a detailed discussion—or, for that matter, *any* discussion—as to how the alleged change in or review of approval requirements *caused* Ranbaxy to miss (by many months) the 30-month statutory tentative approval deadline.

F. FDA Unlawfully Determines, Without Explanation Or Reasoned Basis, That Ranbaxy Is Entitled To 180-Day Exclusivity.

59. On information and belief, FDA has determined that Ranbaxy is eligible for 180-day exclusivity despite Ranbaxy's undisputed failure to obtain tentative approval prior to the 30-month statutory deadline. On information and belief, FDA has determined that Ranbaxy's failure to obtain timely tentative approval was caused by a change in or a review of the requirements for approval of the application imposed after the date on which Ranbaxy's Valsartan Tablet ANDA was filed, and therefore that Ranbaxy has not forfeited its exclusivity for failing to obtain timely tentative approval. On information and belief, there has been no change in or a review of the requirements for approval that directly caused Ranbaxy's failure to obtain timely tentative approval.

60. On September 21, 2012, for the first time, FDA made publicly available its October 25, 2007, Tentative Approval Letter to Ranbaxy.

61. In its October 25, 2007, Tentative Approval Letter, FDA states that it was not addressing issues relating to Ranbaxy's eligibility for 180-day exclusivity. Yet, the Agency nevertheless goes on to state that there had been a change to the USP monograph for Valsartan, published on May 1, 2007, and that the Agency considered that monograph change to be a

change in the requirements for approval imposed after the date on which Ranbaxy's ANDA was filed. (Oct. 25, 2007 Tentative Approval Ltr. for Ranbaxy's Valsartan Tablets at 1).

62. Notably, the USP monograph update/in-process revision referenced by FDA in the October 25, 2007, Tentative Approval Letter was first proposed and published by USP in January-February 2006—*well over a year before Ranbaxy's 30-month tentative approval deadline*. The October 25, 2007, Tentative Approval Letter does not provide any explanation or reasoned basis for why this proposed update constituted a "change" in the approval requirements, or how these proposed changes, that Ranbaxy and FDA were aware of as early as February 2006, directly "caused" or otherwise was "causally connected" to Ranbaxy's failure to meet the 30-month deadline.

63. Because the October 25, 2007, Tentative Approval Letter does not provide any explanation or reasoned basis for why a USP update can constitute a "change" in the approval requirements, or how these proposed changes directly "caused" or were otherwise "causally connected" to Ranbaxy's failure to meet the 30-month deadline, Mylan sought such an explanation from the Agency.

64. At the end of the business day on September 28, 2012, FDA sent Mylan's counsel a letter relating to FDA's refusal to finally approve Mylan's ANDA based upon the Agency's determination that another company is entitled to generic exclusivity (hereinafter, "FDA's September 28th Correspondence").

65. While acknowledging that FDA was refusing to finally approve Mylan's ANDA based upon an award of exclusivity to another company, ***FDA's September 28th Correspondence expressly (and unlawfully) refuses to disclose the basis for FDA's decision***. For example:

- "For the reasons stated below, we are unable to disclose to you whether Ranbaxy is eligible for 180-day exclusivity and/or has forfeited any such exclusivity." (FDA's September 28th Correspondence at 1).

- "Although FDA cannot disclose whether Ranbaxy is eligible for 180-day exclusivity and/or has forfeited such exclusivity, because FDA has tentatively approved Mylan's ANDA for valsartan tablets, it is now public information that FDA has determined that an ANDA sponsor is eligible for 180-day exclusivity that precludes FDA from providing Mylan with final approval at this time." (*Id.* at 4).

- "[W]e cannot provide you the basis on which the Agency determined that the first applicant for valsartan tablets has not forfeited its eligibility for exclusivity because that analysis rested on confidential information contained in that application. FDA appreciates the challenge this presents to you and other parties affected by a forfeiture analysis, but the Agency is nonetheless prohibited at this time from disclosing any additional information regarding the forfeiture decision." (*Id.*)

66. FDA's express refusal to timely and publicly disclose the basis for its determination that Mylan is not entitled to final approval is arbitrary, capricious, an abuse of discretion, and contrary to law.

67. FDA's express refusal to timely and publicly disclose the basis for its determination that Ranbaxy has not forfeited its exclusivity, including a detailed explanation for the Agency's determination that a change directly "caused" or was otherwise "causally connected" to Ranbaxy's failure to meet the 30-month deadline, is arbitrary, capricious, an abuse of discretion, and contrary to law.

68. Indeed, FDA's decision to act without providing the required explanation appears strategically directed to avoid effective judicial review of final agency action.

69. The courts have, in fact, expressly admonished FDA's practice of frustrating judicial review by refusing to timely address generic exclusivity.

70. For example, in *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008) (Bates, J.), FDA sought to frustrate judicial review by refusing to timely address generic exclusivity for a drug called COSOPT®. As Judge Bates observed, FDA's actions harmed the market, the courts, and ultimately the public:

> FDA is creating . . . a situation where there really is no ability to challenge before what is alleged to be irreparable harm occurs. There's no real ability to challenge that exclusivity decision before . . . the floodgates of marketing open. Why does FDA think that's good? The players in the market don't think it's good. . . . The public doesn't think it's good, I don't think. You're not doing anything for the public . . . . The court certainly doesn't think it's good if I get a TRO application which they have preformulated at 3:30 and I have to decide . . . without me even reading your decision, I have to decide whether to enter a TRO just to hold the status quo, which of course is terrible for the public, because . . . it prevents any generic products from getting into the market.

(Oct. 2, 2008 Hr'g Tr. at 9, *Hi-Tech Pharmacal Co., Inc. v. FDA et. al.*, No. 08-1495 ("*Hi-Tech* Oct. 2, 2008 Hr'g Tr.")). When FDA nonetheless refused to comply with the court's request to act in a timely manner, Judge Bates took steps to ensure an opportunity for meaningful judicial review—first scheduling a hearing for the date of the approval deadline (*Hi-Tech*, 587 F. Supp. 2d at 13), and second, imposing a TRO that precluded FDA from approving competing products before the Court could consider an application for injunctive relief:

> [Y]ou're going to be enjoined not to [approve] any further [generic applications] until the Court allows it. ***I'm not going to try to make sense out of this idiotic process that the FDA [is using]. . . . It is, from my perspective, insane what we're going through.*** I'm not going to try to ensure fairness to the parties who are in front of me and have the FDA go and issue an [approval] that allows some other company to go out into the marketplace, and you need to understand that I'm not going to allow that.

(Oct. 22, 2008 Hr'g Tr. at 13, *Hi-Tech Pharmacal Co., Inc. v. FDA et. al.*, No. 08-1495 ("*Hi-Tech* Oct. 22, 2008 Hr'g Tr.") (emphasis added)).

71. In *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010), the D.C. Circuit observed:

> [T]he exclusivity reward that Congress made available as an incentive for patent challenges is time-sensitive, and where there is no material ambiguity about essential facts a court can readily decide whether it has been earned in advance of generic competition's onset. The alternative approach—delaying review until the agency has made its technically tentative decisions final—puts a court in an awkward bind, unless it miraculously manages to resolve the merits issue more or less instantaneously. Apart from that risky and improbable course, there would be two possible stopgaps available to preserve the first-mover advantage. The court could delay *all* generic competition, thereby thwarting the statutory purpose of achieving swift competition by generics (a factor that would in turn weigh against preliminary injunctive relief under the "public interest" component of the standard test). Or it could delay the entrance of the exclusivity claimant's generic rivals into the market, thereby giving the claimant precisely the relief it seeks, simply in order to allow the court time to decide whether such relief was warranted. The technical possibility that a judge might embrace one of these highly imperfect alternatives can hardly be thought to protect Teva from the hardship made likely by delayed review.

Id. at 1311 (emphasis in original).

72. FDA here not only refused to act on a timely basis, but also expressly refuses to provide any explanation—let alone a reasoned one—for its decision that the statutory 30-month tentative approval deadline does not apply in the case of Valsartan Tablets.

73. Neither Mylan nor the judicial system need to accept FDA's "trust me" approach to administering a statute that it is charged with lawfully administering. Indeed, such a response directly runs afoul of FDA's obligations under Hatch-Waxman and the APA.

74. FDA's final decision granting Ranbaxy 180-day exclusivity, and FDA's final decision refusing to grant final approval of Mylan's Valsartan Tablet ANDA was arbitrary, capricious, an abuse of discretion, and contrary to law. Ranbaxy forfeited its exclusivity under

FDA's own precedent and prior interpretation and application of the FFDCA. FDA thus had no lawful basis to award Ranbaxy exclusivity or to deny Mylan final approval.

75. Mylan has exhausted its administrative remedies. Any additional effort to seek administrative relief from the Agency would result in irreparable prejudice and harm to Mylan.

Count I
(Violation of the FFDCA and APA)

76. Mylan repeats and realleges the foregoing paragraphs as though fully alleged herein.

77. Ranbaxy is the "first applicant" to submit a paragraph IV ANDA for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, and was eligible for 180-day generic marketing exclusivity with respect to that ANDA, provided that Ranbaxy secured tentative approval within 30-months of filing that ANDA and all other statutory requirements were met.

78. Ranbaxy failed to receive tentative approval prior to the statutory 30-month forfeiture deadline, and no statutory exception to forfeiture applies. Any eligibility for exclusivity has therefore been forfeited.

79. FDA has awarded Ranbaxy exclusivity for its Valsartan Tablet ANDA and has impermissibly found that Ranbaxy did not forfeit its 180-day exclusivity for Valsartan Tablets, despite Ranbaxy's failure to obtain tentative approval within the 30-month statutory timeframe.

80. FDA has taken this final agency action without providing any reasoned basis for its decision, and has in fact, expressly refused to provide such an explanation.

81. FDA has, in fact, failed to provide any reason, let alone a rational one, for finding that the USP monograph update was a "change" or "review" in the approval requirements that directly "caused," or was otherwise "causally connected to," Ranbaxy's failure to meet the 30-month statutory deadline.

82. FDA's final decision to afford Ranbaxy exclusivity, and to withhold final approval to Mylan's Valsartan Tablet ANDA based on such exclusivity, is arbitrary, capricious, an abuse of discretion, and not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FFDCA.

83. FDA's final decision to afford Ranbaxy exclusivity, and to withhold final approval to Mylan's Valsartan Tablet ANDA based on such exclusivity, constitutes final agency action for which Mylan is entitled to judicial review and relief under the APA.

84. Mylan is suffering, and will continue to suffer, significant and irreparable harm from the Agency's unlawful grant of exclusivity to Ranbaxy and refusal to immediately approve Mylan's Valsartan Tablet ANDA upon expiration of the pediatric exclusivity associated with the '578 patent.

85. Mylan has no adequate remedy at law.

Count II
(Relief Pending Review, 5 U.S.C. § 705)

86. Mylan repeats and realleges the foregoing paragraphs as though fully alleged herein.

87. Under 5 U.S.C. § 705, to prevent significant and irreparable harm to Mylan, Mylan is entitled to interim injunctive relief staying any and all approvals of, or other agency action on, Valsartan Tablet ANDAs pending resolution of this matter on the merits, and any appeal therefrom.

Request for Relief

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against the federal Defendants, as follows:

(a) Entry of judgment declaring that FDA's decision that Ranbaxy is entitled to 180-day exclusivity for generic Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, is arbitrary, capricious, an abuse of discretion, and contrary to law;

(b) Entry of judgment declaring that FDA's decision refusing to grant final approval of Mylan's ANDA No. 90-866 for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg is arbitrary, capricious, an abuse of discretion, and contrary to law;

(c) Entry of judgment setting aside and vacating FDA's decision awarding Ranbaxy 180-day exclusivity for generic Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, and refusing to grant final approval of Mylan's ANDA No. 90-866 for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg;

(d) Entry of an injunction enjoining FDA from affording Ranbaxy 180-day exclusivity for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg;

(e) Entry of an injunction enjoining FDA from awarding 180-day exclusivity for Valsartan Tablets;

(f) Entry of an injunction directing FDA to immediately grant final approval of Mylan's ANDA No. 90-866 for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg;

(g) In the alternative, entry of an interim injunction staying all approvals of ANDAs for Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg, pending resolution of this action and any appeal therefrom;

(h) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(i) Such other and further relief as the Honorable Court deems just and proper.

Dated: October 2, 2012.

Respectfully submitted,

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By: _____
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