IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WATSON LABORATORIES, INC., Morris Corporate Center III 400 Interpace Parkway Parsippany, NJ 07054 Plaintiff, v. KATHLEEN SEBELIUS, Secretary of Health and Human Services, 200 Independence Avenue, S.W. Washington D.C. 20201, MARGARET A. HAMBURG, M.D., Commissioner of Food and Drugs, United States Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993, and UNITED STATES FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendants.	Civil Action No. ___-_____

COMPLAINT

Plaintiff Watson Laboratories, Inc. ("Watson") for its complaint against the defendants, Kathleen Sebelius, Secretary of Health and Human Services; Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, United States Food and Drug Administration; and the United States Food and Drug Administration (collectively "FDA"), alleges as follows:

NATURE OF THE ACTION

1. On July 15, 2003, Watson submitted an Abbreviated New Drug Application ("ANDA") under the generic drug provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), seeking FDA approval to market generic Pioglitazone Hydrochloride tablets, 15 mg, 30 mg, and 45 mg ("pioglitazone"). Pioglitazone is currently marketed by Takeda North America, Inc. (with its parent and affiliates, "Takeda") under the trade name Actos®.

2. On September 9, 2003, FDA informed Watson that Watson's ANDA had been received and was acceptable for filing with an effective date of July 15, 2003. This letter confirmed that Watson's ANDA was substantially complete as of July 15, 2003.

3. Watson's ANDA contained Paragraph IV certifications challenging Takeda's patents on pioglitazone. No other filer submitted a Paragraph IV certification prior to Watson's July 15, 2003 submission. To encourage applicants to submit ANDAs with Paragraph IV certifications as early as possible, the FDCA provides that the first ANDA applicant to file an ANDA with a Paragraph IV certification is entitled to a 180-day period of generic marketing exclusivity.

4. Watson and two other pioglitazone ANDA applicants, Mylan, Inc. ("Mylan") and Ranbaxy Laboratories, Ltd. ("Ranbaxy") subsequently entered into protracted patent litigation with Takeda. In March 2010, that litigation was settled. The settlement agreement between Watson and Takeda provided that Takeda would grant a non-exclusive license to the pioglitazone patents as of August 17, 2012.

5. Watson has been actively preparing to launch its pioglitazone product on August 17, 2012, in keeping with the Takeda settlement and Watson's position as the first

ANDA filer with the right to 180-day exclusivity, and communications from FDA to the effect that Watson's ANDA was moving toward August approval.

6. Despite the fact that no other filer submitted an ANDA containing a Paragraph IV certification prior to Watson's ANDA, in August 2012 FDA informed Watson that FDA has decided to grant another ANDA filer or filers 180-day exclusivity, to the exclusion of Watson's ANDA, and that approval of Watson's ANDA will accordingly be delayed (the "FDA Decision").

7. As set forth more fully herein, the FDA Decision is arbitrary, capricious and contrary to law, and will cause Watson harm for which Watson is entitled to declaratory and injunctive relief, including but not limited to:

a. Issuance of judgment declaring that the FDA Decision is arbitrary, capricious and contrary to law; and

b. Issuance of an injunction directing FDA not to approve any other ANDA for pioglitazone prior to the approval of Watson's ANDA;

c. Alternatively, if FDA grants final approval to any other ANDA for pioglitazone, issuance of an injunction directing FDA to grant final approval to Watson's ANDA.

THE PARTIES

8. Plaintiff Watson is a corporation organized and existing under the laws of Nevada, having a principal place of business in Parsippany, New Jersey.

9. Defendant Kathleen Sebelius ("Sebelius") is a party in her official capacity as the Secretary of the United States Department of Health and Human Services, having offices at 200 Independence Avenue, S.W., Washington, D.C. Defendant

Sebelius has been delegated the authority by the Congress of the United States to administer the FDCA.

10. Defendant Margaret A. Hamburg, M.D., ("Hamburg") is a party in her official capacity as the Commissioner of Food and Drugs, the head of and highest ranking official within FDA, which has offices at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. Defendant Sebelius, as Secretary of Health and Human Services, has delegated to defendant Hamburg the authority to administer the drug approval provisions of the FDCA through FDA.

11. Defendant FDA is an agency within the Public Health Service, which is a part of Health and Human Services. 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

JURISDICTION AND VENUE

12. This case arises under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, et seq.; the FDCA, 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) (commonly referred to as the "Hatch-Waxman Act") (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. The FDA Decision is a final agency action, which presents an actual controversy for which Watson is entitled to review and relief under 5 U.S.C. § 701 et seq.

14. Watson has standing to maintain this action pursuant to the APA, as a legal entity that has suffered a legal wrong and has been adversely affected by final agency action, as complained of herein.

15. There exists an actual, justiciable case or controversy between Watson and FDA regarding the FDA Decision as to which Watson requires: (i) a declaration of rights by this Court; and (ii) injunctive relief against FDA.

16. This Court has jurisdiction over the subject matter of this action under, inter alia, 28 U.S.C. §§ 1331, 1361, 2201.

17. This Court has personal jurisdiction over defendants Sebelius, Secretary of Health and Human Services; Hamburg, Commissioner of Food and Drugs; and FDA, in that the agency and the individual defendants conduct substantial business in the district.

18. Venue is proper in this judicial district by virtue of 28 U.S.C. § 1391.

FACTUAL BACKGROUND

New Drugs and Patent Listing Requirements

19. Before marketing a new drug in the United States, a manufacturer must submit an NDA to FDA, and FDA must approve it. Once approved, new drugs generally are referred to as brand name drugs because they are marketed under a trade name or trademark for the drug product rather than the chemical name for the active ingredient in the drug product.

20. In addition to the technical data submitted in an NDA, a brand name drug manufacturer is required to submit to FDA information on each patent that claims the drug or a method of using the drug that is the subject of the NDA with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, sale or importation of the drug product. A brand name drug manufacturer should submit patent information – the patent's number and its expiration date – in connection with its NDA if the patent claims

a drug or claims a method of using the drug covered by the NDA. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53.

21. Once FDA approves an NDA, FDA lists the patent information submitted by the brand name drug manufacturer in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). 21 U.S.C. § 355(b)(1).

Generic Drugs and Patent Certification Requirements

22. A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark for the drug product.

23. Before marketing a generic drug in the United States, a manufacturer must submit an ANDA to FDA, and FDA must approve it. An ANDA applicant must show that its generic drug is bioequivalent to the previously approved brand name drug.

24. Generic drugs typically enjoy a significant price advantage over their brand name counterparts. Consequently, generic drugs are frequently prescribed in an effort to control healthcare costs. Generic drugs represent a substantial and increasing portion of the medicines used in the United States.

25. A generic drug manufacturer seeking FDA approval for a generic version of a brand name drug product must file one of four certifications with FDA: (i) that the brand name drug manufacturer has not filed patent information with FDA; or, for each patent listed in the Orange Book as claiming the brand name drug or a method of use for which the ANDA applicant is seeking approval, (ii) that the patent has expired; (iii) that the patent expires on a date before which the generic manufacturer is seeking to market its generic product; or (iv) that the patent claiming the brand name drug is invalid,

unenforceable, or will not be infringed by the manufacturer, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)(a)(4). The final certification is commonly referred to as a Paragraph IV certification.

26. If an ANDA applicant submits an ANDA with a Paragraph IV certification to FDA, it is required to notify the patent owner and the holder of the approved NDA (both of which are usually the brand name drug manufacturer). The filing of an ANDA with a Paragraph IV certification is deemed to be an act of infringement, which can be grounds for a brand name drug manufacturer to commence an action for patent infringement against the ANDA applicant. See 35 U.S.C. § 271(e)(2).

27. As an alternative to certification under Paragraph IV, an ANDA filer may submit a "Section viii" statement to the effect that it is not seeking approval for a use claimed by the listed patent. 22 U.S.C. § 505(j)(2)(A)(viii). FDA permits ANDAs to submit either a Paragraph IV certification or a Section viii statement, as appropriate, but not both.

Generic Marketing Exclusivity

28. In order to encourage generic market entry, the first ANDA applicant to file a "substantially complete" ANDA with a Paragraph IV certification (the "First Filer") is given a 180-day period in which it is the only applicant allowed to market a generic version of the brand name product. This is commonly referred to as the 180-day exclusivity period.

29. Specifically, the relevant statute (as it existed at the time of Watson's July 15, 2003 filing, prior to the amendments of the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003 ("MMA")) provides that, if an ANDA with a Paragraph IV certification "is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of one of two triggering events, including the date of the first commercial marketing by the First Filer. 21 U.S.C § 355(j)(5)(B)(iv); see also 21 C.F.R. § 314.107(c)(1) (where an ANDA is for a generic copy of the same listed drug for which one or more substantially complete ANDAs containing a Paragraph IV certification were previously submitted, approval of the subsequent ANDA will be effective no sooner than 180 days from the beginning of the exclusivity period).

30. Where two or more ANDAs with Paragraph IV certifications are filed simultaneously, the period of exclusivity is shared between the simultaneous filers. This is commonly referred to as "shared exclusivity."

Watson's ANDA for Pioglitazone

31. Takeda is the holder of the patents for pioglitazone, including patents relating to the pharmaceutical composition of pioglitazone and its use as a monotherapy (U.S. Patent Nos. 5,965,584 and 6,329,404) (collectively, the "Composition Patents") and patents relating to pioglitazone's use as a combination therapy (U.S. Patent Nos. 6,150,383, 6,150,384, 6,166,042, 6,166,043, 6,172,090, 6,211,205, 6,271,243 and 6,303,640) (collectively, the "Combination Therapy Patents"). Takeda markets pioglitazone under the trade name Actos®. Pioglitazone is widely prescribed for the treatment of type 2 diabetes.

32. On July 15, 2003, the first day on which ANDAs for generic pioglitazone could lawfully be filed, Watson submitted to the FDA its ANDA No. 76-798 for approval to market generic pioglitazone (the "Watson ANDA"). Watson's ANDA contained Paragraph IV certifications as to both the Composition Patents and the Combination Therapy Patents.

33. Watson's ANDA contained all necessary information under 21 U.S.C. § 355(j)(2)(A) and 21 C.F.R. § 314.94 to be considered "substantially complete."

34. The labeling submitted with the Watson ANDA was limited to the use of pioglitazone as a monotherapy.

35. On or about August 18, 2003, FDA communicated to Watson that because Watson had filed Paragraph IV certifications as to the Combination Therapy Patents, it should revise its labeling to include language regarding pioglitazone as a combination therapy.

36. On or about August 27, 2003, in response to FDA's instructions, Watson submitted a telephone amendment to its ANDA. While Watson indicated that it disagreed with FDA's position that Watson was required to revise its labeling to include combination therapy if it was challenging the Combination Therapy Patents, in the interests of facilitating ANDA review, Watson amended its ANDA, changing its Paragraph IV certifications with respect to the Combination Therapy Patents to Section viii statements, while maintaining its Paragraph IV certifications with respect to the Composition Patents. Watson's amendment was expressly made "without prejudice to its right to reinstate its original Paragraph IV Certifications with the effective date of

original submission on July 15, 2003, should a court or the Agency hold in the future that Paragraph IV Certifications should have been made and/or maintained."

37. On or about September 9, 2003, FDA provided notice to Watson that Watson's ANDA had been received and was acceptable for filing with an effective date of receipt of July 15, 2003. The ANDA was therefore considered by FDA to be "substantially complete" as of July 15, 2003.

38. On or about September 9, 2003, the same day it received FDA's "acceptable for filing" letter, Watson provided a "notice letter" to Takeda as required under the FDCA. Takeda responded by commencing patent litigation against Watson in the U.S. District Court for the Southern District of New York, asserting infringement of both the Composition Patents and the Combination Therapy Patents.

39. On or about December 13, 2005, the FDA informed Watson that the Watson ANDA had been tentatively approved.

Other ANDAs for Pioglitazone

40. In addition to Watson, there were two other contemporaneous ANDA filers for generic pioglitazone, Mylan and Ranbaxy.

41. Mylan filed ANDA No. 76-801, with an effective filing date of July 15, 2003. Ranbaxy filed ANDA No. 76-800.

42. No filer submitted an ANDA for generic pioglitazone prior to July 15, 2003.

The Settlement of the Takeda Litigation

43. After extensive litigation, in which Watson continued to assert, among other defenses, the same defenses that were the basis for Watson's original Paragraph IV certification, in March 2010, Takeda settled its litigation with Watson and the other ANDA filers.

44. The settlement agreement between Takeda and Watson provided in relevant part that Takeda would grant a non-exclusive license to the Composition Patents and the Combination Therapy Patents as of August 17, 2012.

45. Following the settlement, Watson subsequently amended the Watson ANDA to reinstate its Paragraph IV certifications as to the Combination Therapy Patents, revising its labeling accordingly.

46. Mylan and Ranbaxy entered into similar settlements with Takeda in or about March 2010, and were granted licenses to enter the market for generic pioglitazone simultaneously with Watson, on August 17, 2012.

47. On information and belief, subsequent to settling with Takeda, Mylan and Ranbaxy also submitted amended ANDAs, making or reinstating Paragraph IV certifications as to the Combination Therapy Patents.

The FDA's Decision to Grant 180-Day Exclusivity to Another Filer or Filers

48. Watson has been actively preparing to launch its pioglitazone product, with an anticipated sale date of August 17, 2012. Based on the simultaneous filing of the Watson ANDA with Mylan and Ranbaxy's ANDAs, Watson has expected to share the period of 180-day exclusivity with Mylan and Ranbaxy (as well as with a fourth generic manufacturer, Teva Pharmaceuticals ("Teva"), that has been granted a license by Takeda). Consistent with that understanding, on or about July 6, 2012, FDA informed Watson that the Watson ANDA "should be on track for full approval come August."

49. In August 2012, FDA informed Watson for the first time that approval of the Watson ANDA would be delayed. FDA informed Watson it had reached a decision to award another filer or filers a period of 180-day exclusivity, to the exclusion of

Watson's ANDA, and to delay approval of Watson's ANDA until the expiration of that exclusivity period.

50. Watson has urged FDA to reconsider its decision, but in conversations with Watson's counsel, FDA has declined to do so.

The FDA Decision is Arbitrary, Capricious and Contrary to Law

51. FDA has failed to provide any explanation or basis for its determination.

52. The FDA Decision is contrary to the plain language of the FDCA, under which ANDA approval can only be delayed where another ANDA was previously filed with a Paragraph IV certification to the same patents.

53. Watson submitted a substantially complete ANDA with Paragraph IV certifications on July 15, 2003. When Watson filed its ANDA, no other ANDA was previously filed with a Paragraph IV certification to the same patents. Watson did not file an ANDA "for a drug for which a previous application has been submitted" containing a Paragraph IV certification, and there is therefore no basis in the law or regulations for FDA to grant exclusivity to another ANDA or to delay approval of Watson's ANDA.

54. Additionally, to the extent that FDA's decision is based on the determination that Watson has lost eligibility to exclusivity for the Combination Therapy Patents, no other ANDA applicant is entitled to such exclusivity under FDA regulations and practice.

55. Thus, FDA's decision to grant exclusivity to another ANDA, to the exclusion of Watson's ANDA, is arbitrary, capricious, and contrary to law.

Harm to Watson Caused by Delaying its Entry into the Generic Pioglitazone Market

56. Unless it is immediately set aside and/or enjoined, FDA's decision to grant 180-day exclusivity to another filer or filers, and to delay Watson's entry into the pioglitazone market until after the expiration of such period, will cause substantial and irreparable harm to Watson.

57. Prior to notice of the FDA Decision, Watson expected to enter the market for generic pioglitazone on August 17, 2012, alongside one or more of Mylan, Ranbaxy, and Teva. Watson has made substantial investments on that basis, including marketing, inventory, preparation of marketing and sales staff, and formulating market projections and a business plan for the launch of pioglitazone in August 2012. These investments will be lost if Watson's entry into the market is improperly delayed.

58. Based on current projections and preliminary sales data, Watson would lose out on substantial revenues, both in absolute terms and in terms of a percentage of Watson's total annual revenues.

59. Moreover, if Watson is granted shared 180-day exclusivity, Watson's first-mover advantage would allow it to maintain a significantly larger market share even after the expiration of the exclusivity period in comparison to other generic competitors that would be entering the market for the first time.

60. Conversely, if Watson's entry into the market is delayed, while its competitors are permitted exclusive entry to the market, Watson will suffer substantial and irreparable harm. Watson's competitors will enjoy an opportunity to lock up relationships with key customers, putting Watson at a competitive disadvantage that will extend beyond the expiration of the unwarranted period of exclusivity.

61. Watson will also suffer a loss of goodwill and reputational harm if it is unable, as anticipated, to offer generic pioglitazone simultaneously with its competitors' entry to the market. This harm will be severe and long-lasting because, on the basis of the industry-wide belief that Watson would share exclusivity, Watson has agreed to supply as of August 17, 2012 customers accounting for a significant percentage of the market. If these customers are forced to attempt to secure alternative supplies on short notice, Watson's goodwill will be seriously damaged.

62. Even if Watson is subsequently permitted entry to the market, each day that Watson's competitors are permitted exclusive access to the market while Watson is excluded will result in irreparable harm to Watson.

63. Additionally, since Watson's competitors have also likely stocked pioglitazone on the assumption that Watson would enter the market in August 2012, exclusion of Watson from the market will likely result in supply shortfalls for generic pioglitazone, contrary to the public interest.

64. Watson has no adequate remedy at law.

CLAIM FOR RELIEF

65. Watson repeats and realleges paragraphs 1 to 64 of the Complaint.

66. As set forth above, the FDA Decision improperly denies Watson the shared exclusivity to which it is entitled as a First Filer of a substantially complete ANDA containing a Paragraph IV certification, contrary to the plain meaning of the FDCA.

67. Because no other filer submitted a substantially complete ANDA containing a Paragraph IV certification prior to Watson's ANDA, FDA's decision to

award another filer or filers with exclusivity as against Watson is arbitrary, capricious, and contrary to 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 FDCA.

68. The FDA Decision constitutes final agency action that is reviewable by this Court.

69. The FDA Decision will cause Watson irreparable harm unless this Court issues immediate injunctive relief setting it aside, enjoining FDA from granting any other filer exclusivity as against Watson, and compelling FDA to grant Watson the shared exclusivity to which it is entitled as a First Filer.

70. Watson has exhausted its administrative remedies.

71. Watson has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Watson Laboratories, Inc. respectfully requests this Court to enter judgment in its favor against defendants Kathleen Sebelius, Secretary of Health and Human Services; Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, United States Food and Drug Administration; and the United States Food and Drug Administration as follows:

a. Entry of judgment declaring that the FDA Decision is arbitrary, capricious and contrary to law;

b. Entry of an injunction directing FDA not to grant final approval (or cause or allow final approval to be granted) to any other ANDA for pioglitazone prior to granting final approval to the Watson ANDA; and

c. Alternatively, if FDA grants final approval to any other ANDA for pioglitazone, entry of an injunction directing FDA to grant final approval to the Watson ANDA; and

d. Entry of an order awarding Watson its reasonable attorneys' fees and costs of prosecuting this action; and

e. Such other and further relief as the Court deems just and proper.

Date: August 15, 2012

Respectfully submitted,

AXINN, VELTROP & HARKRIDER LLP

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