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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GMBH, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	**Civil Action No. _____**
v.	)	
WATSON LABORATORIES, INC., ACTAVIS, INC., and ACTAVIS PHARMA, INC.	)	
Defendant.	)	

COMPLAINT

Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") for their Complaint against Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Watson") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Watson Laboratories of Abbreviated New Drug Application ("ANDA") No. 203689 with the U.S. Food and Drug

Administration ("FDA") seeking approval to manufacture and sell generic versions of STAXYN® prior to the expiration of U.S. Patent No. 8,613,950 ("the '950 patent").

THE PARTIES

2. Plaintiff Bayer Pharma AG, formerly known as Bayer Schering Pharma AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981.

5. On information and belief, defendant Actavis, Inc. ("Actavis"), formerly known as Watson Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

6. On information and belief, defendant Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, CA 92880 and is a wholly-owned subsidiary of Actavis.

7. On information and belief, defendant Actavis Pharma, Inc. ("Actavis Pharma"), formerly known as Watson Pharma, Inc., is a corporation organized under the laws of Delaware and a wholly-owned subsidiary of Actavis. Actavis Pharma has a place of business at

Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. On information and belief, Watson Laboratories' preparation and submission of ANDA No. 203689 for Watson's Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg (Watson's "ANDA Product") was done at the direction, under the control, and for the direct benefit of Actavis. Upon information and belief, Actavis directed Watson Laboratories to submit ANDA No. 203689.

9. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 203689, Actavis, Watson Laboratories, and Actavis Pharma will act in concert to distribute and sell Watson's ANDA Product throughout the United States and within New Jersey. These three entities are herein collectively referred to as "Watson." Upon information and belief, following any FDA approval of ANDA No. 203689, Watson knows and intends that its ANDA Product will be distributed and sold in the United States and within New Jersey.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Actavis, Watson Laboratories, and Actavis Pharma are subject to personal jurisdiction in New Jersey because, among other things, they regularly transact and/or solicit business in New Jersey, have consented to jurisdiction in New Jersey in cases arising out of their filing of ANDAs, and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here. In addition, each of Actavis (formerly known as Watson Pharmaceuticals) and Actavis Pharma (formerly known as Watson Pharma) has a place of business in New Jersey.

12. On information and belief, Actavis, Watson Laboratories, and/or Actavis Pharma share common employees, officers and/or directors.

13. In its most recent Form 10-K, Actavis describes its facility in Parsippany, New Jersey as its "principal executive offices" and its "global and U.S. headquarters." On information and belief, Actavis organizes its operations into three distinct operating segments: Actavis Pharma, Actavis Specialty Brands, and Anda Distribution.

14. On information and belief, Actavis's "Actavis Pharma" segment is responsible for developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market, and relies on contributions from Actavis, Watson Laboratories, and Actavis Pharma.

15. On information and belief, Watson Laboratories and Actavis Pharma are agents of Actavis and each other, and/or operate in concert as integrated parts of Actavis's "Actavis Pharma" segment.

16. On information and belief, Actavis has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other subsidiaries, Watson Laboratories and Actavis Pharma.

17. On information and belief, Actavis Pharma, acting as the agent of Actavis and Watson Laboratories, distributes and sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, Actavis Pharma and/or Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are at less than arm's length.

18. On information and belief, Actavis and/or Watson Laboratories earns revenue from the distribution in New Jersey by Actavis Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. On information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey. On information and belief, Actavis Pharma, Actavis, and Watson Laboratories will manufacture, market, and/or sell within the United States the generic product described in Watson's ANDA No. 203689 if FDA approval is granted. If ANDA No. 203689 is approved, the generic product charged with infringing the '950 patents would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

19. On information and belief, Actavis (formerly known as Watson Pharmaceuticals), Watson Laboratories, and Actavis Pharma (formerly known as Watson Pharma) participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 203689, the ANDA at issue in this litigation. For instance, by letter dated February 6, 2014, Watson Laboratories directed Plaintiffs to send any written notice regarding confidential access concerning ANDA No. 203689 to Brian Anderson, Esq. at Actavis, Inc., Morris Corporate Center III, 400 Interpace Parkway, Parsipanny, NJ 07054. On information and belief, Mr. Anderson is Senior Counsel – Intellectual Property at Actavis.

20. Although submitted on behalf of Watson Laboratories, Inc., the letter addressed to Plaintiffs and dated February 6, 2014 was sent under the letterhead of "Watson Pharmaceuticals" (which is now Actavis, Inc.) and indicated a return address of Morris

Corporate Center III, 400 Interpace Parkway, Parsipanny, New Jersey 07054. The letter was signed by Joyce Delgaudio, whose primary office, upon information and belief, is located in New Jersey.

21. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

22. STAXYN® (active ingredient vardenafil hydrochloride ("vardenafil HCl")) is a selective inhibitor of cyclic guanosine monophosphate-specific phosphodiesterase type 5. STAXYN® is indicated for the treatment of erectile dysfunction.

23. United States Patent No. 8,613,950, entitled "Pharmaceutical Forms with Improved Pharmacokinetic Properties," was duly and legally issued on December 24, 2013. The '950 patent is attached as Exhibit A to this complaint.

24. Bayer Intellectual Property GmbH is the assignee of the '950 patent.

25. Bayer Pharma AG holds an exclusive license under the '950 patent.

26. Bayer HealthCare Pharmaceuticals Inc. is the holder of New Drug Application No. 200179 for STAXYN®, which has been approved by the FDA. Pursuant to 21 U.S.C. § 355, the '950 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with STAXYN®.

27. One or more claims of the '950 patent, incorporated by reference herein, cover STAXYN®.

28. By letter dated February 6, 2014 (the "Notice Letter"), Watson Laboratories notified Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. that Watson had submitted to the FDA ANDA No. 203689 for

Watson's ANDA Product. This product is a generic version of STAXYN®.

29. The purpose of ANDA No. 203689 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, or sale of Watson's ANDA Product prior to the expiration of the '950 patent.

30. In the Notice Letter, Watson also notified Plaintiffs that, in connection with its ANDA No. 203689, Watson had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), with respect to the '950 patent. Upon information and belief, Watson submitted a Paragraph IV Certification in connection with ANDA No. 203689 asserting that the '950 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Product.

31. The Notice Letter provides no valid basis for concluding that the '950 patent is invalid, unenforceable or not infringed. The Notice Letter also fails to identify any limitation of any claim of the '950 patent that is not met literally by Watson's ANDA Product.

32. In the Notice Letter, Watson notified Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. that Watson's ANDA Product contains vardenafil HCl in the form of an orally disintegrating tablet.

33. On information and belief, in ANDA No. 203689, Watson seeks approval to market and sell Watson's ANDA Product to treat erectile dysfunction.

34. Watson had knowledge of the '950 patent prior to its filing of a Paragraph IV Certification for the '950 patent in connection with ANDA No. 203689.

35. On information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product

immediately and imminently upon approval of ANDA No. 203689, i.e., prior to the expiration date of the '950 patent.

COUNT I – PATENT INFRINGEMENT – '950 PATENT

36. Bayer incorporates each of the preceding paragraphs 1-35 as if fully set forth herein.

37. Watson's ANDA Product contains the chemical compound vardenafil HCl in the form of an orally disintegrating tablet.

38. Watson's submission of ANDA No. 203689 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Product before the expiration of the '950 patent infringed the '950 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 203689.

40. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product would infringe one or more claims of the '950 patent.

41. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 203689.

42. Upon information and belief, use of Watson's ANDA Product in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '950 patent.

43. Upon information and belief, Watson plans and intends to, and will,

actively induce infringement of the '950 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

44. The foregoing actions by Watson constitute and/or will constitute infringement of the '950 patent and active inducement of infringement of the '950 patent.

45. Upon information and belief, Watson has acted with full knowledge of the '950 patent and without a reasonable basis for believing that it would not be liable for infringing the '950 patent or actively inducing infringement of the '950 patent.

46. Unless Watson is enjoined from infringing the '950 patent and/or actively inducing infringement of the '950 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Bayer respectfully requests that judgment be entered in favor of Bayer and against Watson and requests the following relief:

A. A judgment that Watson has infringed the '950 patent;

B. A judgment ordering that the effective date of any FDA approval for Watson to make, use, offer for sale, sell, market, distribute, or import Watson's ANDA Product, or any product that infringes the '950 patent, be not earlier than the expiration date of the '950 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product that infringes the '950 patent, or the inducement of any of the foregoing, prior to the expiration date of the '950 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

D. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product that infringes the '950 patent, prior to the expiration date of the '950 patent, will infringe and actively induce infringement by others of the '950 patent;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of Plaintiffs' costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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Dated: March 21, 2014

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any pending arbitration or administrative proceeding. The patent asserted in this civil action is not the subject of any other action pending in any court. The ANDA filed by Watson is the subject of an action pending in another court involving different, unrelated patents: *Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, C.A. No. 12-517 (GMS) (D. Del.).

Pursuant to Local Civil Rule 40.1, I hereby certify that this civil action does not (1) relate to any property included in a case already pending in this Court; (2) grow out of the same transaction as any case already pending in this Court; or (3) involve the validity or infringement of any patent, copyright or trademark which is involved in a case already pending in this Court.

Respectfully submitted,

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Dated: March 21, 2014