IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GMBH, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
WATSON PHARMACEUTICALS, INC. and WATSON LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. bring this Complaint for patent infringement against Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc., and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly, §§ 271(e)(2) and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 202349, filed by Watson Laboratories, Inc., with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Bayer's Natazia® drug product.

PARTIES

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

3. Plaintiff Bayer Intellectual Property GmbH ("Bayer IP") 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, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare"), formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

5. On information and belief, Defendant Watson Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, Watson Pharmaceuticals, Inc. is in the business of, among other things, developing, manufacturing, and marketing generic copies of branded pharmaceutical products through its operating subsidiary, Defendant Watson Laboratories, Inc.

7. On information and belief, Defendant Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 132 Business Center Drive, Corona, California 92880.

8. On information and belief, Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., and the two have common officers and directors.

9. On information and belief, Watson Pharmaceuticals, Inc. has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other entities, Watson Laboratories, Inc.

10. On information and belief, Watson Pharmaceuticals, Inc. participated in, assisted, and cooperated with Defendant Watson Laboratories, Inc. in all of the acts complained of herein. Hereinafter, Defendants Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. are collectively referred to as "Watson."

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. by virtue of, inter alia, the fact that they regularly transact and solicit business in Delaware and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into Court here.

13. On information and belief, Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. earn revenue from the distribution in Delaware of generic pharmaceutical products that are manufactured by Watson Laboratories, Inc. or other entities. On information and belief, various products for which Watson Laboratories, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware and elsewhere through a link provided on Watson Pharmaceuticals, Inc.'s website.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

15. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 022252, for Natazia®. Natazia® contains, as active ingredients, estradiol valerate

and dienogest. Natazia® tablets have been approved by the FDA to prevent pregnancy in women who elect to use an oral contraceptive, and to treat heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.

16. Bayer HealthCare markets Natazia® in the United States under Bayer Pharma's exclusive license in the field of women's healthcare, general medicine, and specialty medicine.

17. Natazia® tablets are sold in the United States by Bayer HealthCare as a 28-day oral contraceptive regimen that contains 2 tablets comprising 3 mg estradiol valerate, plus 5 tablets comprising 2 mg estradiol valerate and 2 mg dienogest, plus 17 tablets comprising 2 mg estradiol valerate and 3 mg dienogest, plus 2 tablets comprising 1 mg estradiol valerate, plus 2 placebo tablets.

18. On information and belief, Watson submitted to the FDA ANDA No. 202349 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic version of Bayer HealthCare's Natazia® tablets.

19. On information and belief, and consistent with their practice with respect to other generic products, Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. acted in concert to prepare and submit ANDA No. 202349 to the FDA.

20. On information and belief, the composition of the product that is the subject of Watson's ANDA is for oral contraception in a human female and is a 28-day oral contraceptive regimen that contains 2 tablets comprising 3 mg estradiol valerate, plus 5 tablets comprising 2 mg estradiol valerate and 2 mg dienogest, plus 17 tablets comprising 2 mg estradiol

valerate and 3 mg dienogest, plus 2 tablets comprising 1 mg estradiol valerate, plus 2 placebo tablets.

21. On information and belief and consistent with their practice with respect to other generic products, following any FDA approval of an ANDA, Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. will act in concert to distribute and sell Watson's oral-contraceptive products for ANDA No. 202349 throughout the United States, including within Delaware. On information and belief, Watson knows and intends that its ANDA products for ANDA No. 202349 will be distributed and sold in the United States, including within Delaware.

22. The patent-in-suit is United States Patent No. 8,071,577 ("the '577 patent") (attached as Exhibit A). Inventors Jan Endrikat and Bernd Düsterberg filed their application for this patent on April 15, 2005. The '577 patent was issued on December 6, 2011. Bayer IP is the current owner of the '577 patent.

23. On information and belief, on or about December 3, 2012, Watson sent a Notice Letter ("2012 Notice Letter") to Bayer Pharma and Bayer HealthCare purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

24. On information and belief, Watson's 2012 Notice Letter asserts that, in its opinion, the '577 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product.

25. On information and belief, Watson, either deliberately or negligently, delayed in amending its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '577 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product.

26. On information and belief, Watson, either deliberately or negligently, delayed in providing Plaintiffs any notice letter purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto and asserting that, in Watson's opinion, the '577 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product.

CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES PATENT NO. 8,071,577

27. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

28. On information and belief, Watson's ANDA product infringes one or more claims of the '577 patent.

29. The '577 patent covers Bayer HealthCare's Natazia® tablets and has been listed for the product in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") since at least January of 2012.

30. On information and belief, Watson submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '577 patent.

31. On information and belief, Watson has amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '577 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product.

32. By filing and amending its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '577 patent, Watson

has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product will also infringe one or more claims of the '577 patent.

33. On information and belief, when Watson amended its ANDA, it was aware of the '577 patent and was aware that amending its ANDA with the request for its approval prior to the expiration of the '577 patent constitutes an act of infringement of the '577 patent.

34. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Watson's ANDA shall be a date which is not earlier than May 13, 2026, the current expiration date of the '577 patent, or any later date of exclusivity to which Plaintiffs become entitled. Further, Plaintiffs are entitled to an award of damages and treble damages for any commercial sale or use of Watson's ANDA product, and any act committed by Watson with respect to the subject matter claimed in the '577 patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

35. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Watson has infringed one or more claims of the '577 patent by filing and amending its ANDA relating to Watson's ANDA product containing estradiol valerate and dienogest;

B. A permanent injunction restraining and enjoining Watson and its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in

the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Watson's ANDA product;

C. An order that the effective date of any approval of Watson's ANDA relating to Watson's ANDA product containing estradiol valerate and dienogest be a date which is not earlier than the expiration date of the '577 patent or any later date of exclusivity to which Plaintiffs become entitled;

D. Damages from Watson for any commercial activity constituting infringement of the '577 patent;

E. Judgment that this is an exceptional case under 35 U.S.C. § 285, and an award of Plaintiffs' costs and expenses of suit, including reasonable attorneys' fees for bringing and prosecuting this action; and

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

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