IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. bring this Complaint for patent infringement against Defendants Lupin Ltd. and Lupin Pharmaceuticals, 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, 35 U.S.C. §§ 271(b), 271(e)(2), and 281. This action relates to the Abbreviated New Drug Application ("ANDA") No. 203307, filed by Lupin Ltd., with the United States Food and Drug Administration ("FDA") for approval to market generic versions 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 Lupin Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

6. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation incorporated under the laws of the Commonwealth of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market.

7. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd.

8. On information and belief, and consistent with their practice with respect to other generic products, Lupin Ltd. and Lupin Pharmaceuticals, Inc. acted in concert to prepare and submit ANDA No. 203307 to the FDA.

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

10. On information and belief and consistent with their practice with respect to other generic products, following any FDA approval of an ANDA, Lupin Ltd. and Lupin Pharmaceuticals, Inc. will act in concert to distribute and sell Lupin's oral-contraceptive products for ANDA No. 203307 throughout the United States, including within Delaware. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. know and intend that Lupin's ANDA products for ANDA No. 203307 will be distributed and sold in the United States, including within Delaware.

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 Lupin Pharmaceuticals, Inc. and Lupin Ltd. 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, Lupin Pharmaceuticals, Inc. has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other entities, Lupin Ltd.

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

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

BACKGROUND

16. 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.

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 of estradiol valerate, plus 5 tablets comprising 2 mg estradiol valerate and 2 mg dienogest, plus 17 tablets comprising 2mg estradiol valerate and 3 mg dienogest, plus 2 tablets comprising 1mg estradiol valerate, plus two placebo tablets.

18. On information and belief, Lupin submitted to the FDA ANDA No. 203307 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, the composition of the product that is the subject of Lupin'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 of estradiol valerate, plus 5 tablets comprising 2 mg estradiol valerate and 2 mg dienogest, plus 17 tablets comprising 2mg estradiol valerate and 3 mg dienogest, plus 2 tablets comprising 1mg estradiol valerate, plus two placebo tablets.

20. On information and belief, on or about October 16, 2012, Lupin sent a Notice Letter to Plaintiffs 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.

21. 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 Intellectual Property GmbH is the current owner of the '577 patent.

22. 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.

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

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

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

25. 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").

26. On information and belief, Lupin 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 Lupin's ANDA product before the expiration of the '577 patent.

27. On information and belief, Lupin included in its ANDA 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 Lupin's ANDA product.

28. By filing 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 Lupin's ANDA product before the expiration of the '577 patent, Lupin 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 Lupin's ANDA product will also infringe one or more claims of the '577 patent.

29. 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 Lupin'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 Lupin's ANDA product, and any act committed by Lupin 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).

30. On information and belief, when Lupin filed its ANDA, it was aware of the '577 patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '577 patent constituted an act of infringement of the '577 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

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

B. A permanent injunction restraining and enjoining Lupin 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 Lupin's ANDA product;

C. An order that the effective date of any approval of Lupin's ANDA relating to Lupin'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 Lupin 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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