3IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc., for their Complaint for patent infringement herein against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., 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(e)(2) and 281. This action relates to the Abbreviated New Drug Application ("ANDA") No. 205948, filed by Lupin Ltd., with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Bayer's Safyral® drug product.

PARTIES

2. Plaintiff Merck & Cie ("Merck") is a Swiss partnership having a principal place of business at Weisshausmatte 6460 Altdorf, Switzerland.

3. Plaintiff Bayer Pharma AG ("Bayer Pharma"), formerly known as Schering 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.

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 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

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 B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), 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. ("Lupin Pharmaceuticals") 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 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 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 acted in concert to prepare and submit ANDA No. 205948 to the FDA.

9. On information and belief, Lupin Pharmaceuticals participated in, assisted, and cooperated with Lupin Ltd. in all of the acts complained of herein. Hereinafter, Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. 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 will act in concert to distribute and sell Lupin's oral contraceptive products for ANDA No. 205948 throughout the United States, including within Delaware. On information and belief, Lupin knows and intends that Lupin's ANDA products for ANDA No. 205948 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 Ltd. and Lupin Pharmaceuticals by virtue of, *inter alia*, the fact that they regularly transact and solicit business in Delaware, have consented to jurisdiction in Delaware in cases arising out of the filing of their ANDAs, 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 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 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.

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. 22574 for Safyral®, which contains as active ingredients drospirenone, 17α-ethinylestradiol, and levomefolate calcium. Safyral® tablets have been approved by the FDA to prevent pregnancy in women who elect to use an oral contraceptive, and to provide a daily dose of folate supplementation. Safyral® tablets are sold in the United States by Bayer HealthCare as a 28-day oral contraceptive regimen that contains 21 tablets comprising 3 mg of micronized drospirenone, 0.03 mg of micronized 17α-ethinylestradiol, and 0.451 mg levomefolate calcium plus 7 tablets comprising 0.451 mg levomefolate calcium.

17. On information and belief, Lupin submitted to the FDA ANDA No. 205948 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 Safyral® tablets.

18. 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 contains tablets comprising 3 mg

of drospirenone, 0.03 mg of 17α-ethinylestradiol, and 0.451 mg levomefolate calcium, and tablets comprising 0.451 mg levomefolate calcium.

19. On information and belief, Lupin's ANDA seeks approval of a 28-day oral contraceptive regimen that contains 21 tablets comprising 3 mg of drospirenone, 0.03 mg of 17α-ethinylestradiol, and 0.451 mg levomefolate calcium, and 7 tablets comprising 0.451 mg levomefolate calcium (hereinafter "Lupin's ANDA product").

20. On information and belief, on or about April 10, 2015, Lupin sent a Notice Letter to Plaintiffs Merck 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 U.S. Patent No. 6,441,168 (the "'168 Patent") (attached hereto as Exhibit 1). Inventors Rudolf Müller, Rudolf Moser and Thomas Egger filed their application for this patent on April 17, 2000. The '168 Patent was issued August 27, 2002. Merck is the current owner of the '168 Patent.

22. Bayer Pharma is the exclusive licensee of the '168 Patent for the sectors of gynecology and andrology, for the indications fertility control, hormone therapy and hormone replacement therapy (with the exception of oncological indications). Bayer Pharma is also the exclusive licensee of the '168 Patent for the indications listed above as a primary indication in combination with secondary indications within the same product.

23. Bayer HealthCare markets Safyral® in the United States under Bayer Pharma's exclusive license.

CLAIM FOR PATENT INFRINGEMENT OF
UNITED STATES PATENT NO. 6,441,168

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

25. On information and belief, Lupin's ANDA product infringes one or more claims of the '168 Patent.

26. The '168 Patent covers Bayer HealthCare's Safyral® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

27. 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 '168 Patent.

28. On information and belief, Lupin made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '168 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.

29. 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 '168 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 '168 Patent.

30. 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 April 17, 2020, the current expiration date of the '168 Patent, or any later date of exclusivity to which Plaintiffs become entitled.

31. On information and belief, when Lupin filed its ANDA, it was aware of the '168 Patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '168 Patent constituted an act of infringement of the '168 Patent.

32. 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 '168 Patent by filing its ANDA relating to Lupin's ANDA product containing drospirenone, ethinylestradiol, and levomefolate calcium;

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 drospirenone, ethinylestradiol, and levomefolate calcium, be a date which is not earlier than the expiration date of the '168 Patent or any later date of exclusivity to which Plaintiffs become entitled;

D. Damages from Lupin for any commercial activity constituting infringement of the '168 Patent; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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