IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

WARNER CHILCOTT COMPANY, LLC,
Union St., Road 195, Km. 1.1
Fajardo, Puerto Rico

Plaintiff,

v.

C.A. No. _____

LUPIN ATLANTIS HOLDINGS SA
Mühlentalstrasse 2
8200 Schaffhausen
Schaffhausen, Switzerland

LUPIN LTD.
B/4 Laxmi Towers,
Bandra Kurla Complex, Bandra (E),
Mumbai 400 051 India

LUPIN PHARMACEUTICALS, INC.
111 S. Calvert Street,
21st Floor,
Baltimore, MD 21202
Baltimore City

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC, by its undersigned attorneys, brings this action against Defendants Lupin Atlantis Holdings SA; Lupin Ltd.; and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), and hereby alleges as follows:

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott") is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

2. Upon information and belief, Defendant Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India.

3. Upon information and belief, Defendant Lupin Atlantis Holdings SA ("Lupin Atlantis") is a wholly-owned subsidiary of Lupin Ltd., and is a corporation organized and existing under the laws of Switzerland.

4. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a wholly-owned subsidiary of Lupin Ltd. and is a corporation organized and existing under the laws of the Commonwealth of Virginia. Lupin Pharmaceuticals has a principal place of business located at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

5. Upon information and belief, Lupin Ltd. has engaged in continuous and systemic contacts with the United States by, among other things, filing with the United States Food and Drug Administration ("FDA") Abbreviated New Drug Applications ("ANDAs") to sell various products in the United States. Upon information and belief,

Lupin Ltd. manufactures generic drug products for sale and use in the United States, including in this judicial district.

6. Upon information and belief, Lupin Ltd., Lupin Atlantis, and Lupin Pharmaceuticals are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic pharmaceutical products. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, through their affiliate, agent, and alter-ego Lupin Atlantis, filed the ANDA with FDA that is at issue in this patent infringement suit. Upon information and belief, the acts of Lupin Atlantis complained of herein were done and are being done with the cooperation, participation, and assistance of, and at least in part for the benefit of, Lupin Ltd. and Lupin Pharmaceuticals.

JURISDICTION AND VENUE

7. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355. This Court has subject matter jurisdiction over this action based on 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Lupin Pharmaceuticals by virtue of, at least, its principal place of business in Baltimore, MD.

9. This Court has personal jurisdiction over Lupin Atlantis at least under Federal Rule of Civil Procedure 4(k)(2).

10. This Court has personal jurisdiction over Lupin Ltd. at least under Federal Rule of Civil Procedure 4(k)(2).

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I: CLAIM FOR INFRINGEMENT OF THE '050 PATENT

12. Warner Chilcott LLC is the holder of New Drug Application ("NDA") No. 203667 for Minastrin® 24 Fe, which contains the active ingredients ethinyl estradiol and norethindrone acetate. Minastrin® 24 Fe was approved by FDA on May 8, 2013, and is indicated for use by women to prevent pregnancy. Minastrin® 24 Fe is sold as a 28-day oral contraceptive regimen that includes 24 chewable tablets comprising 1.0 mg norethindrone acetate and 0.020 mg ethinyl estradiol, and 4 chewable ferrous fumarate tablets (placebo).

13. U.S. Patent No. 6,667,050 (the "'050 Patent") entitled "Chewable Oral Contraceptive" was lawfully issued by the United States Patent and Trademark Office on December 23, 2003. A copy of the '050 Patent is attached as Exhibit A.

14. Warner Chilcott is the sole owner of the '050 Patent.

15. The '050 Patent claims, among other things, chewable, palatable oral contraceptive tablets; methods of administering said tablets to a human female; and methods of enhancing compliance with the oral contraception regimen.

16. Minastrin® 24 Fe and its use in accordance with the FDA-approved labeling are covered by the claims of the '050 Patent. The '050 Patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Minastrin® 24 Fe.

17. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, through their affiliate, agent, and alter-ego Lupin Atlantis, submitted ANDA No. 206287 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Minastrin® 24 Fe before the expiration of the '050 Patent. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of such product would infringe the claims of the '050 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

18. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic Minastrin® 24 Fe product for which approval is sought in ANDA No. 206287 would actively induce and contribute to infringement of the '050 Patent, and Defendants would be liable under 35 U.S.C. § 271(b) and/or (c).

19. As part of their ANDA filing, Lupin Ltd. and Lupin Pharmaceuticals, through their affiliate, agent, and alter-ego Lupin Atlantis, have purportedly provided written certification ("Paragraph IV certification") to FDA that the claims of the '050 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of Minastrin® 24 Fe.

20. By letter dated April 24, 2014, Defendants' counsel gave written notice of the certification of invalidity and/or noninfringement of the '050 Patent, alleging that the claims of the '050 Patent are invalid due to obviousness, indefiniteness, and lack of enablement, and that claims 18, 36, and 54 are not infringed by Defendants' generic

Minastrin® 24 Fe product. The letter additionally informed Warner Chilcott that Defendants seek to engage in the commercial manufacture, use, and sale of a product bioequivalent to Minastrin® 24 Fe prior to the expiration of the '050 Patent.

21. Lupin Atlantis has infringed the '050 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 206287 with a Paragraph IV certification and seeking FDA approval of ANDA No. 206287 prior to the expiration of the '050 Patent. Moreover, if Lupin Atlantis commercially manufactures, uses, offers for sale, or sells in the United States, or imports into the United States, Defendants' generic version of Minastrin® 24 Fe, it would further infringe the '050 Patent under 35 U.S.C. § 271(a), (b), and/or (c). Upon approval of ANDA No. 206287, Lupin Atlantis will actively induce and/or contribute to infringement of the '050 Patent under 35 U.S.C. § 271(b) and/or (c).

22. Lupin Pharmaceuticals and Lupin Ltd. are jointly and severally liable for any infringement of the '050 Patent by virtue of submitting ANDA No. 206287 through their agent, affiliate, and alter-ego Lupin Atlantis. Upon information and belief, Lupin Pharmaceuticals and Lupin Ltd. contributed to, aided, abetted, and/or induced the submission of ANDA No. 206287 and its Paragraph IV certification to FDA. Additionally, upon information and belief, Lupin Pharmaceuticals will market and/or distribute Defendants' generic version of Minastrin® 24 Fe if ANDA No. 206287 is approved by FDA.

23. Lupin Pharmaceuticals and Lupin Ltd.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 206287 and its Paragraph IV certification to FDA constitute infringement of the '050 Patent under 35

U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharmaceuticals and/or Lupin Ltd. commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States, Defendants' generic version of Minastrin® 24 Fe, they would further infringe the '050 Patent under 35 U.S.C. § 271(a), (b), and/or (c). Upon approval of ANDA No. 206287, Lupin Pharmaceuticals and Lupin Ltd. will actively induce and/or contribute to infringement of the '050 Patent under § 271(b) and/or (c).

24. This case is an exceptional one, and Warner Chilcott is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

25. Warner Chilcott will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '050 Patent. Warner Chilcott does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Warner Chilcott respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '050 Patent by submitting ANDA No. 206287;

B. A permanent injunction restraining and enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '050 Patent, including the product described in ANDA No. 206287;

C. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 206287, or inducing or contributing to such conduct, would constitute infringement of the '050 Patent by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. An order that the effective date of any approval of Defendants' ANDA be a date that is not earlier than the expiration of the '050 Patent or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled;

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

F. Costs and expenses in this action; and

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

Dated: June 6, 2014

Respectfully submitted,

/s/ Benjamin C. Block
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