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

WARNER CHILCOTT COMPANY, LLC, Plaintiff, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	)	C. A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC, by its undersigned attorneys, brings this action against Defendants 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 Pharmaceuticals, Inc. ("LPI") is a wholly-owned subsidiary of Lupin Ltd. and is a corporation organized and existing under the laws of the Commonwealth of Virginia. LPI has a principal place of business located at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

4. Upon information and belief, LPI is doing business in New Jersey, is registered to do business in New Jersey, has engaged in continuous and systemic contacts with New Jersey, and purposefully availed itself of this forum by, among other things, shipping, using, offering to sell, selling, or causing others to use, offer to sell or sell pharmaceutical products in New Jersey and deriving substantial revenue from such activities.

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 Abbreviated New Drug Applications 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. and LPI 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, the acts of Lupin Ltd. 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, LPI.

7. Lupin Ltd. and LPI have previously availed themselves of the U.S. District Court for the District of New Jersey by, *inter alia*, filing litigation and asserting counterclaims in this District.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over LPI by virtue of the fact that it conducts business in the State of New Jersey, has purposefully availed itself of the rights and benefits of New Jersey law and this Court, and has engaged in substantial and continuing contacts with the State by selling a range of generic pharmaceutical products within the United States generally and New Jersey specifically.

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(b), (c) and (d) and 1400(b).

COUNT I
CLAIM FOR INFRINGEMENT OF THE '050 PATENT

12. Watson Labs. Inc. is the holder of New Drug Application ("NDA") No. 22-573 for Generess™ Fe, which contains the active ingredients norethindrone and ethinyl estradiol. Generess™ Fe was approved by the United States Food and Drug Administration ("FDA") on December 22, 2010, and is indicated for the prevention of pregnancy in women who elect to use it as a method of contraception. Generess™ Fe is sold as a 28-day oral contraceptive regimen that includes 24 chewable tablets comprising 0.8 mg norethindrone and 0.025 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" 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, a chewable, palatable oral contraceptive tablet, a method of administering said tablet to a human female and a method of enhancing compliance with the oral contraception regimen.

16. The '050 patent covers the use of Generess™ Fe in accordance with the labeling approved by the FDA and is listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product.

17. Upon information and belief, Lupin submitted to the FDA an Abbreviated New Drug Application ("ANDA") filed under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of Generess™ Fe prior to the expiration of the '050 patent.

18. Upon information and belief, Lupin's ANDA directed to its proposed generic Generess™ Fe product has been assigned No. 20-3448.

19. Upon information and belief, the active tablet composition that is the subject of Lupin's ANDA contains 0.8 mg norethindrone and 0.025 mg ethinyl estradiol in a chewable, palatable tablet form for oral contraception in a human female.

20. Upon information and belief, Lupin's ANDA was submitted with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '050 patent is purportedly invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Lupin's ANDA product.

21. Upon information and belief, Lupin sent notice of that certification to Warner Chilcott on or about October 28, 2011. Warner Chilcott received that notice letter on or about October 31, 2011.

22. By filing the Defendants' ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the manufacture, use or sale of their ANDA product before the expiration of the '050 patent, Lupin committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Further, the manufacture, use or sale of Lupin's proposed ANDA product will also infringe one or more claims of the '050 patent.

23. Upon approval of Lupin's ANDA, Lupin will actively induce and/or contribute to infringement of the '050 patent.

24. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Lupin's ANDA be a date that is not earlier than the expiration date of the '050 patent, or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) Judgment that Lupin Ltd. and Lupin Pharmaceuticals, Inc. have infringed one or more claims of the '050 patent by submitting ANDA No. 20-3448;

(b) A permanent injunction be issued restraining and enjoining Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions that would infringe, induce infringement of and/or contribute to infringement of the '050 patent;

(c) An order that the effective date of any approval of Lupin's ANDA 20-3448 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; and

(d) Such other and further relief as the Court may deem just and proper.

December 12, 2011

Respectfully submitted,

s/William J. O'Shaughnessy
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