IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

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

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott") is a corporation 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, Lupin conducts business in the State of Delaware.

JURISDICTION AND VENUE

5. 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).

6. This Court has personal jurisdiction over Lupin by virtue of the fact that Lupin conducts business in the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with the State.

7. To the extent that Lupin Ltd. successfully contends it is not doing business in the State of Delaware, jurisdiction over Lupin Ltd. in Delaware is also proper under Federal Rule of Civil Procedure 4(k)(2).

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

COUNT I
CLAIM FOR INFRINGEMENT OF THE '050 PATENT

9. Warner Chilcott is the holder of New Drug Application ("NDA") No. 21-490, for Femcon® Fe (previously Ovcon® 35 Fe), which contains the active ingredients norethindrone and ethinyl estradiol, in a chewable, palatable tablet form. Femcon® Fe was approved by the United States Food and Drug Administration ("FDA") on November 14, 2003 and is indicated for the prevention of pregnancy in women who elect to use it as a method of contraception. Femcon® Fe is sold as a 28-day oral contraceptive regimen that contains 21 chewable tablets comprising 0.4 mg norethindrone and 0.035 mg ethinyl estradiol followed by 7 ferrous fumarate tablets (placebo).

10. 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.

11. Warner Chilcott owns the entire right, title and interest in the '050 patent.

12. 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.

13. The '050 patent covers Femcon® Fe and has been listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product.

14. 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 Femcon® Fe prior to the expiration of the '050 patent.

15. Upon information and belief, Lupin's ANDA directed to its proposed generic Femcon® Fe product has been assigned No. 91-332.

16. Upon information and belief, the composition that is the subject of Lupin's ANDA contains 0.4 mg norethindrone, 0.035 mg ethinyl estradiol and ferrous fumarate in a chewable, palatable tablet form for oral contraception in a human female.

17. 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.

18. Upon information and belief, Lupin sent notice of that certification to Warner Chilcott on or about July 30, 2009. Warner Chilcott received Lupin's notice letter on or about July 31, 2009.

19. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the manufacture, use or sale of its ANDA product before the expiration of the '050 patent, Lupin has 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.

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

21. 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 becomes entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) Judgment that Lupin has infringed one or more claims of the '050 patent by submitting ANDA No. 91-332;

(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 and/or contribute to infringement of the '050 patent;

(c) An order that the effective date of any approval of Lupin's ANDA 91-332, be a date that is not earlier than the expiration of the '050 patent, or any later expiration of exclusivity to which Plaintiff becomes entitled; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Karen Jacobs Louden

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington , DE 19899
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Warner Chilcott Company, LLC

OF COUNSEL:

Dominick A. Conde
Steven C. Kline
John D. Carlin
Joanna L. Garelick
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112
(212) 218-2100

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