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

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| WARNER CHILCOTT COMPANY, LLC, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | |
| | ) | C. A. No. _____ |
| LUPIN LTD. 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, 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 systematic 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. 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

7. 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).

8. 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.

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

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

## BACKGROUND

11. Warner Chilcott is the holder of New Drug Application ("NDA") No. 22-501, for Lo Loestrin® Fe, which contains the active ingredients norethindrone acetate and ethinyl estradiol. Lo Loestrin® Fe was approved by the United States Food and Drug Administration ("FDA") on October 21, 2010 and is indicated for the prevention

of pregnancy in women who elect to use it as a method of contraception. Lo Loestrin® Fe is sold as a 28-day oral contraceptive regimen which includes 24 active tablets comprising 1 mg norethindrone acetate and 0.01 mg ethinyl estradiol, 2 active tablets comprising 0.01mg ethinyl estradiol, followed by 2 ferrous fumarate tablets (placebo).

12. U.S. Patent No. 5,552,394 ("the '394 patent") entitled "Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy" lawfully issued from the United States Patent and Trademark Office on September 3, 1996. A copy of the '394 patent is attached as Exhibit A.

13. Warner Chilcott is the sole owner of the '394 patent.

14. The '394 patent claims, inter alia, a method of female contraception which comprises monophasicly administering a combination of estrogen and progestin in which the daily amounts of estrogen and progestin are equivalent to about 0.001 to 0.035 mg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, and in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate for 24 days of a 28 day cycle.

15. U.S. Patent No. 7,704,984 ("the '984 patent") entitled "Extended Estrogen Dosing Contraceptive Regimen" lawfully issued from the United States Patent and Trademark Office on April 27, 2010. A copy of the '984 patent is attached as Exhibit B.

16. Warner Chilcott is the sole owner of the '984 patent.

17. The '984 patent claims, inter alia, a method of female contraception which comprises administering (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is

selected from norethindrone acetate or norethindrone and 5 to 15 mcg of ethinyl estradiol for 24 days, (b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days, and (c) a third composition that is a placebo, wherein the sequential administration of the first composition, the second composition and the third composition, is performed on a daily basis over a 28 day cycle.

18. The '394 and '984 patents each cover the use of Lo Loestrin® Fe in accordance with the respective labeling approved by the FDA and are listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product.

19. 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 Lo Loestrin® Fe prior to the expirations of the '394 patent and the '984 patent.

20. Upon information and belief, Lupin's ANDA directed to its proposed generic Lo Loestrin® Fe product has been assigned No. 20-3113.

21. Upon information and belief, the composition that is the subject of Lupin's ANDA is directed to 24 tablets containing 1 mg norethindrone and 0.01 mg ethinyl estradiol, 2 tablets containing 0.01 mg ethinyl estradiol and 2 tablets containing ferrous fumarate (placebo).

## COUNT I
## CLAIM FOR INFRINGEMENT OF THE '394 PATENT

22. Paragraphs 1 through 21 are repeated.

23. 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 '394 patent is purportedly invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Lupin's ANDA product.

24. Upon information and belief, Lupin sent notice of that certification to Warner Chilcott on or about July 19, 2011. Warner Chilcott received Lupin's notice letter on or about July 20, 2011.

25. 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 '394 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 '394 patent.

26. Upon approval of Lupin's ANDA, Lupin will actively induce and/or contribute to infringement of the '394 patent.

27. 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 '394 patent, or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled.

28. This is an exceptional case, and Warner Chilcott is entitled to its costs and reasonable attorney fees.

## COUNT II
## CLAIM FOR INFRINGEMENT OF THE '984 PATENT

29. Paragraphs 1 through 28 are repeated.

30. 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 '984 patent is purportedly invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Lupin's ANDA product.

31. Upon information and belief, Lupin sent notice of that certification to Warner Chilcott on or about July 19, 2011. Warner Chilcott received Lupin's notice letter on or about July 20, 2011.

32. 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 '984 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 '984 patent.

33. Upon approval of Lupin's ANDA, Lupin will actively induce and/or contribute to infringement of the '984 patent.

34. 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 '984 patent, or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled.

35. This is an exceptional case, and Warner Chilcott is entitled to its costs and reasonable attorney fees.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) Judgment that Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. have infringed one or more claims of the '394 patent by submitting ANDA No. 20-3113;

(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 '394 patent;

(c) An order that the effective date of any approval of Lupin's ANDA No. 20-3113, be a date that is not earlier than the expiration of the '394 patent, or any later expirations of exclusivity to which Plaintiff is or becomes entitled;

(d) Judgment that Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. have infringed one or more claims of the '984 patent by submitting ANDA No. 20-3113;

(e) 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 '984 patent;

(f) An order that the effective date of any approval of Lupin's ANDA No. 20-3113, be a date that is not earlier than the expiration of the '984 patent, or any later expirations of exclusivity to which Plaintiff is or becomes entitled;

(g) Declaring this to be an exceptional case and awarding Plaintiff its attorney fees under 35 U.S.C. § 285; and

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

September 1, 2011

Respectfully submitted,

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matters in controversy in this action partially overlap with the subject matter of another action pending in this Court in that there is one patent common to the two litigations (U.S. Patent No. 5,552,394). That other pending action was filed on June 2, 2011 and is captioned *Warner Chilcott Company, LLC v. Mylan, Inc., Mylan Pharmaceuticals Inc. and Famy Care Ltd.*, 3:11-cv-03262 (JAP)(TJB) (the "Mylan Action"). This action differs from the Mylan action, however, in that (a) there is a second patent at issue in this action that is not at issue in the Mylan Action (U.S. Patent No. 7,704,984), (b) the products involved in the two actions have different dosage strengths and employ different regimens, and (c) the defendants are different.

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