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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, Plaintiff, v. MYLAN INC., MYLAN PHARMACEUTICALS INC. and FAMY CARE LTD., Defendants.

C. A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC by its undersigned attorneys, brings this action against Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Famy Care Ltd. (collectively "Defendants"), 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 Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized and existing under the laws of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharms is a wholly-owned subsidiary of Mylan Inc.

4. Upon information and belief, Defendant Famy Care Ltd. ("Famy Care") is organized and exists under the laws of the Republic of India and has a principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai – 400 001, India.

5. Upon information and belief, Mylan Inc. is doing business in New Jersey. Upon information and belief Mylan Inc. is registered to do business in New Jersey. Mylan Inc., directly, or through its subsidiaries, including Mylan Pharms, has engaged in continuous and systematic 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, and by filing counterclaims in New Jersey.

6. Upon information and belief, Mylan Pharms is doing business in New Jersey. Upon information and belief Mylan Pharms is registered to do business in New Jersey. Mylan Pharms has engaged in continuous and systematic 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, and by filing counterclaims in New Jersey.

7. Upon information and belief, Famy Care has engaged in continuous and systematic contacts with the United States by, among others things, on or about August 7, 2008, entering into an agreement with Mylan Inc. to file ANDAs for generic contraceptive products and to supply such products to customers in the United States.

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 Mylan Inc. and Mylan Pharms, because, *inter alia*, Mylan Inc. and Mylan Pharms have purposefully availed themselves of the rights and benefits of New Jersey law. Upon information and belief, Defendants Mylan Inc. and Mylan Pharms engage in the sale of a range of generic pharmaceutical products within the United States generally and New Jersey specifically.

10. This Court has personal jurisdiction over Famy Care 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) and (c), and 28 U.S.C. § 1400(b).

BACKGROUND

12. 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 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 0.01 mg ethinyl estradiol, followed by 2 ferrous fumarate tablets (placebo).

13. 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 A.

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

15. 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.

16. The ’984 patent covers the use of Lo Loestrin® Fe in accordance with the respective 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, Famy Care, together with its U.S. agent, Mylan Pharms, 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 (the “Defendants’ ANDA Product”) prior to the expiration of the ’984 patent.

18. Upon information and belief, Defendants’ ANDA directed to its proposed generic Lo Loestrin® Fe product has been assigned No. 20-5049.

19. Upon information and belief, the composition that is the subject of Defendants’ ANDA is directed to 24 tablets containing 1 mg norethindrone acetate 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 ’984 PATENT

20. Upon information and belief, Defendants’ 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 Defendants’ ANDA Product.

21. Upon information and belief, Defendants sent notice of that certification to Warner Chilcott on or about September 19, 2013. Warner Chilcott received Defendants’ notice letter on or about September 20, 2013.

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