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

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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), (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, 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 Generess™ Fe prior to the expiration of the '050 patent.

18. Upon information and belief, Defendants' ANDA directed to its proposed generic Generess™ Fe product has been assigned No. 20-3371.

19. Upon information and belief, the active tablet composition that is the subject of Defendants' 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, 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 '050 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, Famy Care and Mylan Pharms sent notice of that certification to Warner Chilcott on or about October 10, 2011. Warner Chilcott received that notice letter on or about October 11, 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, Famy Care and its U.S. agent, Mylan Pharms, committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Further, the manufacture, use or sale of Defendants' proposed ANDA product will also infringe one or more claims of the '050 patent.

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

24. Upon information and belief, the acts of Mylan Pharms and Famy Care complained of herein were done and are being done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of, Mylan Inc.

25. 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 Defendants' 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 Defendants have infringed one or more claims of the '050 patent by submitting ANDA No. 20-3371;

(b) A permanent injunction be issued restraining and enjoining Defendants Mylan Inc., Mylan Pharmaceuticals Inc. and Famy Care Ltd., 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 Defendants' ANDA 20-3371, 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.

November 22, 2011

Respectfully submitted,

s/William J. O'Shaughnessy
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Attorneys for Plaintiff Warner Chilcott Company, LLC

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 are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

November 22, 2011

Respectfully submitted,

s/William J. O'Shaughnessy
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