

Arnold B. Calmann (abc@saiber.com)

Jakob B. Halpern (jbh@saiber.com)

SAIBER LLC

One Gateway Center, Suite 1000

Newark, New Jersey 07102-5311

T: (973) 622-3333

Timothy H. Kratz (tkratz@mcguirewoods.com)

Robert L. Florence (rflorence@mcguirewoods.com)

George J. Barry III (gbarry@mcguirewoods.com)

Brie L.B. Buchanan (bbuchanan@mcguirewoods.com)

Jessica M. Hauth (jhauth@mcguirewoods.com)

MCGUIREWOODS LLP

1230 Peachtree Street N.E., Suite 2100

Atlanta, Georgia 30309-3534

T: (404) 443-5500

Attorneys for Defendants/Counterclaim Plaintiffs

Mylan Pharmaceuticals Inc. and Mylan Inc.

**IN THE 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.)

Civil Action No. 3:13-cv-06560-JAP-TJB

DOCUMENT FILED ELECTRONICALLY

**ANSWER, DEFENSES AND COUNTERCLAIMS OF
MYLAN INC. AND MYLAN PHARMACEUTICALS INC. TO
PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Mylan Inc. (“Mylan”) and Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”) (collectively, “Mylan” or “Defendants”) answer the Complaint of Plaintiff

Warner Chilcott Company, LLC (“Warner Chilcott” or “Plaintiff”), as follows:

RESPONSE TO ALLEGATIONS PERTAINING TO 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.

ANSWER: Upon information and belief, Mylan admits that Plaintiff has offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico. Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 1 of the Complaint, and, on that basis, denies those allegations.

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.

ANSWER: Mylan admits that Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania with an office located at 1500 Corporate Drive, Canonsburg, PA 15317. Mylan denies the remaining allegations in paragraph 2.

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.

ANSWER: Mylan admits that Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia with an office at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, and that Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. Mylan denies the remaining allegations in paragraph 3.

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.

ANSWER: Upon information and belief, Mylan admits Famy Care is a corporation organized under the laws of India with a place of business at 3rd Floor, Brady House, 12/14,

Veer Nariman Road, Fort, Mumbai - 400 001, India. Mylan denies the remaining allegations in paragraph 4.

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.

ANSWER: Mylan admits that Mylan Inc. is registered to do business in New Jersey, but denies that Mylan Inc. is a proper party to this litigation. Mylan denies the remaining allegations contained in paragraph 5.

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.

ANSWER: Mylan admits that Mylan Pharmaceuticals is registered to do business in New Jersey. Mylan Pharmaceuticals does not contest jurisdiction for the limited purpose of this action only. Mylan denies the remaining allegations in paragraph 6.

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.

ANSWER: Mylan denies the allegations in paragraph 7 of the Complaint.

RESPONSE TO ALLEGATIONS PERTAINING TO 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).

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Mylan admits that Plaintiff purports to bring this action under the laws of the United States and that this Court has subject matter jurisdiction over the claims this action, but denies that Mylan Inc. is a proper party to this action. Mylan denies the remaining allegations in paragraph 8 of the Complaint.

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.

ANSWER: Mylan Pharmaceuticals does not contest personal jurisdiction for the purposes of this action only. Mylan denies the remaining allegations in paragraph 9 of the Complaint.

10. This Court has personal jurisdiction over Famy Care at least under Federal Rule of Civil Procedure 4(k)(2).

ANSWER: Mylan lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 10, and, on that basis, denies those allegations.

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

ANSWER: Mylan does not contest venue in this judicial district for the limited purpose of this action, but specifically denies that this judicial district is the most appropriate and convenient venue for this action. Mylan denies the remaining allegations in paragraph 11 of the Complaint.

RESPONSE TO ALLEGATIONS PERTAINING TO 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).

ANSWER: Mylan admits that Warner Chilcott is indicated in the records of the FDA as the holder of NDA No. 22-501 for Lo Loestrin[®] Fe, which contains the active ingredients norethindrone acetate and ethinyl estradiol, and which was approved by the FDA on October 21, 2010 and is indicated for the prevention of pregnancy in women. Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 12 of the Complaint, and, on that basis, denies those allegations.

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.

ANSWER: Mylan admits that the ’984 patent is entitled “Extended Estrogen Dosing Contraceptive Regimen” and purports to have issued from the United States Patent and Trademark Office on April 27, 2010. Mylan further admits that Plaintiff purports to attach a copy of the ’984 patent as Exhibit A to the Complaint. Mylan denies that the ’984 patent was lawfully issued.

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