

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

ORTHO-MCNEIL-JANSSEN)
PHARMACEUTICALS, INC.)

Plaintiff,)

v.)

Civil Action No. _____

MYLAN INC., MYLAN)
PHARMACEUTICALS INC. and)
FAMY CARE LTD.)

Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMJPI”), by its attorneys, for its complaint against Mylan Inc., Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”), and Famy Care Ltd. (“Famy Care”) (collectively, “Defendants”), alleges as follows:

The Parties

1. Plaintiff OMJPI is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

2. Upon information and belief, Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317. Upon information and belief, Defendant Mylan Inc. operates administrative offices in this judicial district, and manufactures numerous generic drugs for sale

and use throughout the United States, including in this judicial district, alone and/or through its wholly owned subsidiary and agent, Defendant Mylan Pharmaceuticals.

3. Upon information and belief, Defendant Mylan Pharmaceuticals is a West Virginia corporation and a wholly-owned subsidiary and agent of Defendant Mylan Inc. with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505. Upon information and belief, Mylan Pharmaceuticals is registered to do business in the State of New Jersey and has identified Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey, 08628 as its registered agent for service of process in this District. Upon information and belief, Defendant Mylan Pharmaceuticals manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone and/or through its parent and principal, Mylan Inc.

4. Upon information and belief, Defendant Famy Care is an Indian business entity with its principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai - 400 001, India. Upon information and belief, Defendant Famy Care manufactures, markets and sells generic pharmaceutical products, including generic contraceptive products. Upon information and belief, on or about August 6, 2008, Famy Care entered into an agreement with Mylan Inc. pursuant to which the two companies would develop and supply generic oral contraceptives to customers in the United States.

5. Upon information and belief, Defendant Mylan Pharmaceuticals is the U.S. Agent for Famy Care with respect to numerous Abbreviated New Drug Applications (“ANDAs”) held by Famy Care and on file with the U.S. Food and Drug Administration (“FDA”), including but not limited to ANDA Nos. 20-2132, 20-0493, and 20-2086, relating to generic oral contraceptive products. Upon information and belief, Mylan Pharmaceuticals and Famy Care

have entered into an agreement whereby Mylan Pharmaceuticals will distribute in the United States, including New Jersey, at least the product for which approval is sought by ANDA No. 20-2132, if such ANDA is approved by the FDA.

Jurisdiction and Venue

6. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271(e) and 355.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Mylan Inc., Mylan Pharmaceuticals, and Famy Care by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a corporation having its principal place of business in New Jersey, Plaintiff OMJPI. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. Mylan Inc. is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, Mylan Inc.'s presence in New Jersey, both through itself and through its wholly-owned subsidiary and agent, Mylan Pharmaceuticals, and its widespread and continuous contacts with New Jersey, including but not limited to its operation of offices in New Jersey, its sales of products in New Jersey and derivation of substantial revenues therefrom, and its filing of claims and counterclaims in this judicial district.

10. Mylan Pharmaceuticals is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, Mylan Pharmaceuticals' presence in New Jersey, as evidenced by

Mylan Pharmaceuticals' qualification to do business in New Jersey, its designation of an agent for service of process in New Jersey, and its widespread and continuous contacts with New Jersey, including but not limited to its sales of products in New Jersey and derivation of substantial revenues therefrom, and its filing of claims and counterclaims in this judicial district.

11. Famy Care is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, Famy Care's filing of counterclaims in this judicial district and Famy Care's presence in New Jersey through its designated U.S. Agent and distributor, Mylan Pharmaceuticals, and its generic oral contraceptive development and supply partner, Mylan, Inc.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Count 1: Patent Infringement

13. OMJPI incorporates by reference the allegations contained in paragraphs 1 through 12 above.

14. United States Patent No. 6,214,815 ("the '815 Patent") entitled "TRIPHASIC ORAL CONTRACEPTIVE" was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on April 10, 2001. OMJPI is the owner of the '815 Patent. A copy of the '815 Patent is attached hereto as Exhibit A.

15. OMJPI currently markets a prescription oral contraceptive product under the trademark ORTHO TRI-CYCLEN LO®. ORTHO TRI-CYCLEN LO® is covered by the claims of the '815 Patent.

16. OMJPI is the holder of an approved New Drug Application ("NDA") covering ORTHO TRI-CYCLEN LO®.

17. Upon information and belief, Famy Care, either directly or through its U.S. Agent, Mylan Pharmaceuticals, submitted ANDA No. 20-2132 to the FDA, seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of ORTHO TRI-CYCLEN LO® before the expiration of the '815 Patent.

18. As part of its ANDA filing, Famy Care, either directly or through its U.S. Agent, Mylan Pharmaceuticals, provided written certification to the FDA purporting that the claims of the '815 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Famy Care's generic version of ORTHO TRI-CYCLEN LO®.

19. By letter dated October 4, 2010, Mylan Pharmaceuticals gave written notice of Famy Care's certification of invalidity and/or noninfringement of the '815 Patent, alleging that the '815 Patent is invalid, and informing OMJPI that Famy Care seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to ORTHO TRI-CYCLEN LO® prior to the expiration of the '815 Patent.

20. Famy Care has infringed the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 20-2132 with a Paragraph IV certification and seeking FDA approval of ANDA No. 20-2132 prior to the expiration of the '815 Patent.

21. Mylan Pharmaceuticals is jointly and severally liable for any infringement of the '815 Patent. Upon information and belief, Mylan Pharmaceuticals participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 20-2132 and its Paragraph IV certification to the FDA. Mylan Pharmaceuticals' participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 20-2132 and its Paragraph IV certification to the FDA constitutes infringement of the '815 Patent under 35 U.S.C. § 271(e)(2)(A).

22. Mylan Inc. is jointly and severally liable for any infringement of the '815 Patent. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 20-2132 and its Paragraph IV certification to the FDA. Mylan Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 20-2132 and its Paragraph IV certification to the FDA constitutes infringement of the '815 Patent under 35 U.S.C. § 271(e)(2)(A).

23. This case is an exceptional one, and OMJPI is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

24. OMJPI will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '815 Patent. OMJPI does not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, OMJPI seeks the following relief:

A. A judgment that Defendants have infringed the '815 Patent under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 20-2132 can be no earlier than the expiration date of the '815 Patent, or any later expiration of exclusivity for the '815 Patent to which OMJPI is or becomes entitled;

C. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 20-2132;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 20-2132 would constitute infringement of the '815 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

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