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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., Plaintiff, v. MYLAN PHARMACEUTICALS, INC., MYLAN INC., and FAMY CARE LTD., Defendants.	Civil Action No.

COMPLAINT

Plaintiff Teva Women's Health, Inc. ("Teva Women's Health") for its Complaint against Defendants Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals"), Mylan Inc., and Famy Care Ltd. ("Famy Care") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, Sections 1 *et seq.*

THE PARTIES

2. Plaintiff Teva Women's Health is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Teva Women's Health is a proprietary pharmaceutical company that has been an innovator in the area of women's health. Teva Women's Health focuses on researching, developing, and providing patients with an array of female healthcare products, with particular emphasis on developing and marketing products that serve the reproductive and menopausal needs of women.

3. On information and belief, Defendant Famy Care is a corporation organized under the laws of India, with a principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai - 400 001, India.

4. On information and belief, Defendant Mylan Inc. is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Dr., Canonsburg, PA 15317.

5. On information and belief, Defendant Mylan Pharmaceuticals is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505 and is a subsidiary of Defendant Mylan Inc. 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.

6. On information and belief, Defendant Mylan Pharmaceuticals is the U.S. Agent for Famy Care Ltd.

7. On information and belief, Defendant Famy Care manufactures, markets and sell generic pharmaceutical products, including generic contraceptive products. On or about August 6, 2008, Defendant Famy Care entered into a partnership with Defendant Mylan Inc. to supply generic oral contraceptives to customers in the United States.

8. On information and belief Mylan Inc. and Mylan Pharmaceuticals manufacture, market and sell generic pharmaceutical products. Mylan Inc. and Mylan Pharmaceuticals distribute their generic pharmaceutical products throughout the United States and in this District. Accordingly, this Court has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over Defendants Mylan Pharmaceuticals, Mylan Inc. and Famy Care, because, *inter alia*, Mylan Pharmaceuticals, Mylan Inc. and Famy Care have purposefully availed themselves of the rights and benefits of New Jersey law. Upon information and belief, Defendants Mylan Pharmaceuticals, Mylan Inc. and Famy Care engage in the sale of a range of generic pharmaceutical products within the United States generally and the State of New Jersey specifically.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because Defendants Mylan Pharmaceuticals, Mylan Inc. and Famy Care are subject to personal jurisdiction in this District.

BACKGROUND

12. On November 10, 2009, the United States Patent and Trademark Office ("USPTO") duly and legally issued U.S. Patent No. 7,615,545 ("the '545 patent"), entitled "Oral Contraceptives to Prevent Pregnancy and Diminish Premenstrual Symptomatology," to Duramed Pharmaceuticals, Inc., now known as Teva Women's Health. The '545 patent names Robert G. Bell, Carole Ben-Maimon, and Beata Iskold as inventors. The '545 patent is valid and enforceable. Teva Women's Health is the sole owner of the '545 patent and has the sole right to sue and to recover for any past, present or future infringement of that patent. The '545 Patent will expire on June 15, 2023. A copy of the '545 patent is attached hereto as Exhibit A.

13. The '545 patent is directed to, *inter alia*, a method of female contraception that reduces the number of menstrual periods per year and that comprises administering a combination of estrogen and progestin for 81-89 consecutive days, followed by administering a dosage consisting essentially of estrogen for a period of 2-8 days.

14. On October 24, 2008, the FDA approved Teva Women's Health's New Drug Application ("NDA") No. 22-262, allowing Teva Women's Health to sell an extended regimen oral contraceptive product in the United States under the trade name LoSeasonique®. The approved use of LoSeasonique® is covered by claims of the '545 patent. The LoSeasonique® product includes 84 combination pills containing 20 µg of ethinyl estradiol and 100 µg of levonorgestrel as the active ingredients and 7 pills containing 10 g of ethinyl estradiol as the active ingredient.

15. The '545 patent is listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") as covering the LoSeasonique® product.

MYLAN'S ACTS GIVING RISE TO THIS ACTION

16. By letter dated January 29, 2010 ("Notice Letter"), Defendant Mylan Pharmaceuticals, U.S. Agent for Famy Care, notified Teva Women's Health that Defendant Famy Care had submitted Abbreviated New Drug Application ("ANDA") No. 20-0493 to the FDA seeking approval to manufacture, sell, and distribute a generic version of Teva Women's Health's LoSeasonique® extended regimen contraceptive product.

17. According to the Notice Letter, the purpose of Famy Care's filing of the ANDA is to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, and sale of a generic version of LoSeasonique® prior to the expiration of the '545 patent. Famy Care contends that its generic version of LoSeasonique® is bioequivalent to Teva Women's Health's branded LoSeasonique® product.

18. As described in the Notice Letter, Famy Care's generic version of LoSeasonique® includes combination tablets that contain a combination of ethinyl estradiol, 20 μg, and levonorgestrel, 100 μg and unopposed estrogen tablets that contain 10 μg of ethinyl estradiol. Upon information and belief, Famy Care's generic version of LoSeasonique® includes between 81 to 89 combination tablets and between 2 to 8 unopposed estrogen tablets.

19. Famy Care submitted its ANDA to the FDA containing a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in its opinion, the '545 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, import, or

sale of the generic version of LoSeasonique® described in its ANDA. By filing the ANDA with the Paragraph IV certification, Famy Care (and its U.S. Agent, Mylan Pharmaceuticals and its parent Mylan Inc.) infringed the '545 patent under 35 U.S.C. § 271(e)(2).

20. On information and belief, Famy Care, Mylan Pharmaceuticals, and/or Mylan Inc. intend to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the generic version of LoSeasonique® described in the ANDA (including, commercial sale of such a product in the State of New Jersey) prior to the expiration of the '545 patent in the event that the FDA approves Famy Care's ANDA.

21. The Notice Letter includes a statement of the legal and factual basis for its belief that the '545 patent is invalid or that the claims of the '545 patent will not be infringed by the manufacture, use or sale of Mylan's proposed ANDA product. Notably, the Notice Letter does not disclose any detailed basis for any allegation that the '545 patent or any claim therein is unenforceable.

22. Upon information and belief, Famy Care, Mylan Inc. and Mylan Pharmaceuticals intend to continue to pursue approval of the ANDA by the FDA.

23. On information and belief, Famy Care, Mylan Inc, and Mylan Pharmaceuticals were aware of the '545 patent when it filed ANDA No. 20-0493 including the Paragraph IV certification.

24. Teva Women's Health commenced this action against Mylan within 45 days of the date it received the Notice Letter dated January 29, 2010 from Mylan Pharmaceuticals regarding Famy Care's submission of its ANDA containing the Paragraph IV certification to the FDA.

COUNT I: PATENT INFRINGEMENT OF U.S. PATENT NO. 7,615,545

25. Paragraphs 1 through 24 are incorporated by reference as if restated fully herein.

26. Upon information and belief, the filing of Famy Care's ANDA seeking approval to engage in the commercial manufacture, use, or sale, offer for sale and/or importation of a generic version of the LoSeasonique® extended regimen oral contraceptive product prior to the expiration of the '545 patent infringed, and its maintenance of that ANDA continues to infringe, the '545 patent under 35 U.S.C. § 271(e)(2).

27. Upon information and belief, the use of the generic version of LoSeasonique® described in the ANDA in accordance with, and as directed by, the proposed product labeling prior to the expiration of the '545 patent would infringe the '545 patent.

28. Upon information and belief, upon FDA approval of Famy Care's ANDA, Famy Care, Mylan Inc., and Mylan Pharmaceuticals intend to manufacture, use, sell, offer for sale, import and distribute the generic version of the LoSeasonique® described in the ANDA in the United States.

29. Upon information and belief, Famy Care, Mylan Inc., and Mylan Pharmaceuticals know that the generic version of LoSeasonique® described in the ANDA and its product labeling are especially made or adapted for use in infringing the '545 patent and are not suitable for substantial noninfringing use.

30. Unless Famy Care, Mylan Inc., and Mylan Pharmaceuticals are enjoined from infringing the '545 patent, Teva Women's Health will be substantially and irreparably harmed by, and will suffer damages as a result of, Famy Care's, Mylan Inc.'s, and Mylan Pharmaceuticals's actions.

31. Upon information and belief, Famy Care, Mylan Inc., and Mylan Pharmaceuticals acted without a reasonable basis for believing that they would not be liable for infringement of the '545 patent.

32. Famy Care, Mylan Inc., and Mylan Pharmaceuticals's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Teva Women's Health respectfully requests the following relief:

A. A permanent injunction barring Famy Care, Mylan Inc., and Mylan Pharmaceuticals and its officers, agents, and employees, and all persons acting in concert with Famy Care, Mylan Inc., or Mylan Pharmaceuticals, from infringing United States Patent No. 7,615,545 by making, using, selling, offering to sell, marketing, importing, or distributing any oral contraceptive product, including the product described in Famy Care's ANDA No. 20-0493;

B. An order decreeing the effective date of any approval of Famy Care's ANDA No. 20-0493 to be a date which is not earlier than the expiration date of United States Patent No. 7,615,545;

C. A final judgment declaring that Mylan Pharmaceuticals, Mylan Inc., and Famy Care's manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in Mylan ANDA No. 20-0493 will infringe, induce infringement, and contribute to the infringement of United States Patent No. 7,615,545;

D. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285 and an award to Teva Women's Health of its attorneys' fees, costs, and expenses incurred in prosecuting this action; and

E. Such other and further relief as this Court may deem just and proper.

Dated: March 9, 2010

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/s/ Michael E. Patunas

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