IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KV PHARMACEUTICAL COMPANY and FP1096, INC.,	)	
Plaintiffs,	)	
v.	)	C. A. No. _____
PERRIGO ISRAEL PHARMACEUTICALS LTD., PERRIGO COMPANY and FEMMEPHARMA HOLDING COMPANY, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, KV Pharmaceutical Company and FP1096, Inc., by way of complaint against defendants Perrigo Company, Perrigo Israel Pharmaceuticals Ltd., and FemmePharma Holding Company, Inc. allege as follows:

1. Plaintiff KV Pharmaceutical Company ("KV") is a Delaware corporation having its principal place of business at One Corporate Woods Drive, Bridgeton, MO 63044.

2. Plaintiff FP1096, Inc. ("FP1096") is a corporation with offices at One Corporate Woods Drive, Bridgeton, MO 63044.

3. Plaintiff FP1096 is a wholly owned subsidiary of plaintiff KV.

4. Defendant FemmePharma Holding Company, Inc. ("FemmePharma") is a Delaware corporation having its principal place of business at 37 West Avenue, 2nd Floor, Wayne, PA 19087.

5. On information and belief, defendant Perrigo Company ("Perrigo") is a Michigan corporation with a place of business at 515 Eastern Avenue, Allegan, MI 49010.

6. On information and belief, defendant Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli company with a place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

7. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo.

8. On information and belief, Perrigo Israel is dominated by and/or is the alter ego of Perrigo.

9. On information and belief, Perrigo Israel is under the direction, control, and/or influence of Perrigo, both generally and with respect to the particular acts and conduct alleged in this Complaint.

10. On information and belief, Perrigo conducts operations through Perrigo Israel, both generally and with respect to the particular acts and conduct alleged in this Complaint.

11. On information and belief, Perrigo conducts certain pharmaceutical development and manufacturing operations through Perrigo Israel, both generally and with respect to the particular acts and conduct alleged in this Complaint.

12. On information and belief, Perrigo is in the business of developing and manufacturing drug products for use and sale throughout the United States and including in the State of Delaware.

13. On information and belief, Perrigo conducts business and sells various drug products throughout the United States and including in the State of Delaware.

14. On information and belief, Perrigo Israel is in the business of developing and manufacturing drug products for use and sale throughout the United States and including in the State of Delaware.

15. On information and belief, Perrigo Israel conducts business and sells various drug products throughout the United States and including in the State of Delaware.

JURISDICTION AND VENUE

16. This is an action for patent infringement arising under the laws of the United States.

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

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

19. On information and belief, Perrigo, as reported in its 2009 Annual Report, engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of Delaware specifically, including to Wal-Mart, CVS, Safeway, Dollar General, Sam's Club, Costco, and Walgreens pharmacy stores within this judicial district.

20. Defendant Perrigo is subject to personal jurisdiction in this district. On information and belief, Perrigo manufactures, sells, offers for sale, and causes to be supplied or sold throughout the United States various products, including prescription and over-the-counter pharmaceuticals and nutritional products. Perrigo's products are sold by mass merchandisers, food stores, and drug stores throughout the United States, including within this judicial district. On information and belief, Perrigo derives substantial revenue from the sales of those products in this district.

21. Defendant Perrigo Israel, as reported in the 2009 Annual Report of Perrigo, engages in the manufacture and sale of a range of generic pharmaceutical products within the

United States generally and the State of Delaware specifically, including to Wal-Mart, CVS, Safeway, Dollar General, Sam's Club, Costco, and Walgreens pharmacy stores within this judicial district.

22. On information and belief, Perrigo Israel, according to Perrigo Israel's profile in Dun & Bradstreet Israel Ltd., develops and manufactures generic topical drugs for the U.S. market.

23. On information and belief, Perrigo Israel, according the 2009 Annual Report of Perrigo, develops and manufactures pharmaceutical products for the U.S. market as part of the Perrigo R_x Pharmaceuticals Group.

24. On information and belief, pharmaceutical products developed and manufactured by Perrigo Israel for the U.S. market include cetirizine, clobetasol foam, halobetasol ointment and cream, and mesalamine rectal suspension enema.

25. On information and belief, Perrigo acts as an agent of Perrigo Israel with respect to the pharmaceutical products developed and manufactured by Perrigo Israel for the U.S. market.

26. On information and belief, Perrigo Israel regularly transacts business within this judicial district, including but not limited to shipping generic pharmaceuticals to Perrigo from locations outside the United States for distribution by Perrigo within the United States generally, and within this judicial district specifically, including among others, generic cetirizine.

27. On information and belief, annual U.S. sales of cetirizine are approximately $500 million, and Perrigo holds approximately 80% of the generic market for cetirizine.

28. Defendant Perrigo's acts and contacts with this judicial district are attributable to Perrigo Israel for jurisdictional purposes.

29. Defendant Perrigo Israel is subject to personal jurisdiction in this judicial district. On information and belief, Perrigo Israel manufactures, sells, offers for sale, and causes to be supplied or sold throughout the United States various products, including prescription and over-the-counter pharmaceuticals and nutritional products. Perrigo Israel's products are sold by mass merchandisers, food stores, and drug stores throughout the United States, including within this judicial district. On information and belief, Perrigo Israel derives substantial revenue from the sales of those products in this district.

30. Defendants Perrigo and Perrigo Israel have been sued for patent infringement in this judicial district (*see, e.g.*, *Stiefel Research Australia Pty. Ltd. v. Perrigo Co. and Perrigo Israel Pharms. Ltd.*, No. 09-758 (D. Del. filed Oct. 13, 2009); *Stiefel Labs., Inc. v. Perrigo Co. and Perrigo Israel Pharms. Ltd.*, No.10-592 (D. Del. filed July 12, 2010)), and did not contest that they are subject to personal jurisdiction in this district.

31. Defendants Perrigo and Perrigo Israel have engaged in substantial and/or continuous and systematic contacts with the State of Delaware, which satisfy due process and confer personal jurisdiction over these defendants.

32. Defendant FemmePharma is a Delaware corporation and is thus subject to personal jurisdiction in this district.

FACTUAL BACKGROUND

The Drug Approval Process

33. The Food, Drug, and Cosmetic Act ("FD&C Act") requires that before a drug manufacturer can market a new pharmaceutical drug in the United States, it must first submit a New Drug Application ("NDA") to the FDA for approval pursuant to Section 505(b) of the FD&C Act, 21 U.S.C. § 355(b). In addition to the extensive testing and safety information

concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1)(G).

34. The FDA lists this patent information with the approved drug in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book." *See* 21 U.S.C. §§ 355(b)(1) and (c)(1).

35. In 1984 Congress adopted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act." This statute amended the FD&C Act to provide for an Abbreviated New Drug Application ("ANDA"), allowing manufacturers to obtain FDA approval for generic version of previously approved drugs without having to repeat the extensive testing required for a new drug application, as long as certain requirements were met. *See* 21 U.S.C. § 355(j).

36. When submitting an ANDA to the FDA, the generic manufacturer must make one of the following four certifications with respect to the each of the patents listed in the Orange Book for the drug for which the applicant seeks approval: (1) that no patent information has been filed, (2) that the patent has expired, (3) that the patent will expire on a specific date, or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a "Paragraph IV" certification). 21 U.S.C. §355(j)(2)(A)(viii)(I-IV).

37. If a generic drug applicant makes a Paragraph IV certification in its ANDA, the Hatch-Waxman Act requires that the applicant give notice to the patent owner and NDA owner ("Notice Letter"). In addition, in that Notice Letter, the ANDA applicant is required to provide

the patent owner with a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

38. A purpose of a Notice Letter is to inform a patentee of the basis for a Paragraph IV certification so that a patentee may determine, as permitted under the Patent Act, whether to commence an action for infringement of an Orange Book listed patent.

KV's Gynazole-1® Product and the '856 Patent

39. KV is the holder of an approved NDA 019-881 under Section 505(b) of the FD&C Act, 21 U.S.C. § 355(b)(1), for Gynazole-1® (butoconazole nitrate), 2%.

40. On November 30, 1999, the United States Patent and Trademark Office ("PTO") duly and legally issued U.S. Patent 5,993,856 ("the '856 patent"), entitled "PHARMACEUTICAL PREPARATIONS AND METHODS FOR THEIR ADMINISTRATION." The '856 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Gynazole-1. A copy of the '856 patent is annexed hereto as Exhibit A.

41. Defendant FemmePharma is the assignee of the '856 patent.

42. Plaintiff FP1096 holds an exclusive license from FemmePharma to the '856 patent to make, have made, import, export, use, offer for sale, sell, market, distribute, reproduce, and otherwise exploit certain products covered by the claims of the '856 patent, including but not limited to products such as Gynazole-1 and the product that is the subject of ANDA No. 20-0923. The license from FemmePharma includes the right to enforce the '856 patent in the case of an ANDA filing and the right to grant sublicenses.

43. Plaintiff KV holds a exclusive sublicense from FP1096 to the rights granted by FemmePharma to FP1096 with respect to the '856 patent. The sublicense from FP1096 includes the right to enforce the '856 patent and the right to grant sublicenses.

44. On information and belief, Perrigo Israel filed, through Perrigo its agent, ANDA No. 20-0923 with the FDA pursuant to Section 505(j) of the FD&C Act, 21 U.S.C. § 355(j), seeking approval to market a generic version of Gynazole-1. Also on information and belief, the ANDA includes a certification pursuant to Section 505(j)(2)(A)(viii)(IV) of the FD&C Act asserting that the '856 patent is invalid or will not be infringed by the manufacture, use, or sale of defendants Perrigo and Perrigo Israel's generic Butoconazole Nitrate Vaginal Cream USP, 2% product.

45. On June 15, 2010, plaintiff KV and defendant FemmePharma received notice from Perrigo as agent for and on behalf of Perrigo Israel that Perrigo Israel had filed ANDA No. 20-0923 containing a Paragraph IV Certification with respect to the '856 patent.

46. On information and belief, Perrigo participated in, contributed to, aided, abetted, and/or induced the submission of ANDA No. 20-0923 and its Section 505(j)(2)(A)(viii)(IV) certification to the FDA. The ANDA notification sent to KV on behalf of Perrigo Israel was composed on Perrigo letterhead and signed by an Assistant General Counsel of Perrigo. On information and belief, Perrigo will participate in the marketing and selling of the proposed generic product described in ANDA No. 20-0923 if it is approved for sale in the United States. On information and belief, Perrigo will participate in the sale, offer for sale, and will cause the proposed generic product described in ANDA No. 20-0923 to be offered for sale or sold throughout the United States generally, and the State of Delaware specifically.

47. This suit is being filed within 45 days of receipt by plaintiff KV and defendant FemmePharma of the Paragraph IV notice.

48. As assignee of the '856 and the exclusive licensor of the '856 patent to plaintiffs, defendant FemmePharma is jointly interested with, and contractually obligated to cooperate with, plaintiffs in this cause of action, including without limitation joining this action as coplaintiff if necessary. Although requested to join as coplaintiff, FemmePharma has not, as of the date of the filing of this action, agreed to join. For that reason, FemmePharma is joined as a defendant.

COUNT I – INFRINGEMENT OF U.S. PATENT 5,993,856

49. Plaintiffs incorporate by reference the preceding averments set forth in paragraphs 1 through 48.

50. Defendants Perrigo and Perrigo Israel have infringed one or more claims of the '856 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 20-0923 seeking approval to market a generic version of a Butoconazole Nitrate Vaginal Cream USP, 2% prior to expiration of the patent.

51 Defendants Perrigo and Perrigo Israel manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Butoconazole Nitrate Vaginal Cream USP, 2% described in ANDA No. 20-0923 would also infringe, directly or indirectly, one or more claims of the '856 patent.

52. Perrigo's participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 20-0923 and its Paragraph IV certification to the FDA also constitutes infringement of the '856 patent.

53. On information and belief, unless enjoined, Perrigo will, without authority, manufacture and/or import into the United States Perrigo Israel's generic Butoconazole Nitrate

Vaginal Cream USP, 2% described in ANDA No. 20-0923 and/or act as distributor of the product within the United States upon Perrigo Israel receiving FDA approval.

54. Perrigo's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Butoconazole Nitrate Vaginal Cream USP, 2% described in ANDA No. 20-0923 would infringe, directly, or indirectly, one or more claims of the '856 patent.

55. Plaintiffs will be irreparably harmed by defendants Perrigo and Perrigo Israel's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

56. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4).

REQUEST FOR RELIEF

WHEREFORE, plaintiffs KV Pharmaceutical Company and FP1096, Inc., demand judgment against defendants Perrigo Company, Perrigo Israel Pharmaceuticals Ltd., and FemmePharma Holding Company, Inc. as follows:

(a) That defendants Perrigo and Perrigo Israel have infringed one or more claims of the '856 patent;

(b) That the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Butoconazole Nitrate Vaginal Cream USP, 2% described in ANDA No. 20-0923 would infringe one or more claims of the '856 patent;

(c) That the effective date of any approval of ANDA No. 20-0923 for Butoconazole Nitrate Vaginal Cream USP, 2% be no earlier than the expiration date of the '856 patent and any additional periods of exclusivity;

(d) That defendants Perrigo and Perrigo Israel, their officers, agents, servants, and employees, and other persons who are in active concert or participation with them, from engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of defendants' Butoconazole Nitrate Vaginal Cream USP, 2%;

(e) That defendant FemmePharma be realigned as plaintiff in this cause of action and compelled to comply with its obligation to cooperate with plaintiffs in this action;

(f) That this is an exceptional case entitling plaintiffs to an award of reasonable attorneys' fees, together with interest, and costs of the action, pursuant to 35 U.S.C. § 285; and

(g) That the Court grant such other and further relief as may be appropriate.

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