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

ABBOTT PRODUCTS, INC., UNIMED PHARMACEUTICALS, LLC, and BESINS HEALTHCARE INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
PERRIGO COMPANY, and PERRIGO ISRAEL PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Abbott Products, Inc. ("Abbott"), Unimed Pharmaceuticals, LLC ("Unimed"), and Besins Healthcare Inc. ("Besins") allege as follows for their complaint against Defendants Perrigo Company, and Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") (collectively "Defendants"):

THE PARTIES

1. Plaintiff Abbott Products, Inc. is a corporation organized and existing under the laws of the State of Georgia, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Plaintiff Unimed Pharmaceuticals, LLC, which is a wholly-owned subsidiary of Abbott Products, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Plaintiff Besins Healthcare Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170.

4. On information and belief, Defendant Perrigo Company is a Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan, 49010.

5. On information and belief, Defendant Perrigo Israel is an Israeli corporation with its principal place of business at 29 Lehi Street, Bnei Brak, 51200, Israel.

NATURE OF THE ACTION

6. This is an action for infringement of U.S. Patent No. 6,503,894 ("the '894 Patent"), titled "Pharmaceutical Composition and Method for Treating Hypogonadism." This action relates to New Drug Application ("NDA") No. 203098 submitted in the name of Perrigo Israel to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Abbott's AndroGel® (testosterone gel) 1%, 2.5 g and 5 g products, and 1.25 g activation (Perrigo's "Generic AndroGel®"), which act constitutes an act of infringement under 35 U.S.C. § 271(e)(2) that is subject to the provisions of the Hatch Waxman Act.

SUBJECT MATTER JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

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

PERSONAL JURISDICTION

10. This court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with New Jersey and contacts with New Jersey in connection with its submission of their NDA, as set forth below, and for other reasons that will be developed and presented to the Court if personal jurisdiction is challenged.

11. Perrigo Company, as reported in its 2010 Annual Report on behalf of itself and its subsidiaries (collectively "Perrigo"), operates as a "global healthcare supplier that develops, manufactures and distributes," *inter alia*, over-the-counter and generic prescription pharmaceutical products. As described in that Annual Report, one of Perrigo's business segments is "R_x Pharmaceuticals." On information and belief, Perrigo Israel, which is a wholly-owned subsidiary of Perrigo Company, is part of Perrigo's R_x Pharmaceuticals segment.

12. According to Perrigo's 2010 Annual Report, its "U.S.-based customers are major wholesalers, including Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, including Walgreens, Wal-Mart, CVS, Rite Aid" and others. Perrigo's "[g]eneric prescription drugs are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as [over the counter] pharmaceuticals and nutritional products." On information and belief, Perrigo Company and Perrigo Israel intend to sell Perrigo's Generic AndroGel® through these same retail outlets in New Jersey, including at least Walgreens, Wal-Mart, CVS, and Rite Aid stores.

13. On information and belief, Perrigo Company directs the activities of the other Perrigo entities, including Perrigo Israel, and is directly responsible for sales of Perrigo products to customers in New Jersey, from which Perrigo Company derives substantial revenue.

14. On information and belief, Perrigo Company, directly or through related companies, has engaged in substantial and continuous contacts with New Jersey which satisfy due process and confer personal jurisdiction over Perrigo Company in New Jersey on the basis of general jurisdiction.

15. On information and belief, Perrigo Israel develops and manufactures pharmaceutical products for the United States market, and has developed and manufactured such products, including cetirizine tablets and syrup, clobetasol foam, halobetasol ointment and cream, imiquimod cream, and mesalamine rectal suspension enema, which are all among Perrigo's major pharmaceutical products according to its 2010 Annual Report. On information and belief, Perrigo Israel derives substantial revenue from the sale of Perrigo products to customers in New Jersey.

16. As further evidence of personal jurisdiction, Perrigo Company has been sued for patent infringement in this district and has not contested personal jurisdiction (*see, e.g.*, C.A. Nos. 3:06-cv-4715, 3:07-cv-5136, 3:08-cv-1909, and 3:10-cv-4838). Perrigo Company has further admitted to personal jurisdiction in this district (C.A. No. 3:06-cv-4715).

17. As further evidence of personal jurisdiction, Perrigo Israel has stipulated that it is subject to jurisdiction in the District of New Jersey (C.A. No. 2:10-cv-0937).

18. On information and belief, Perrigo Israel, directly or in concert with related companies, has engaged in substantial and continuous contacts with New Jersey which

satisfy due process and confer personal jurisdiction over Perrigo Israel in New Jersey on the basis of general jurisdiction.

19. On information and belief, and consistent with their practice with respect to other generic products, Perrigo Company and Perrigo Israel acted in concert to prepare and submit NDA No. 203098. Perrigo Israel has represented that it signed NDA No. 203098 with Perrigo Company acting as its authorized U.S. agent.

20. On information and belief, Perrigo Company and Perrigo Israel are subject to specific personal jurisdiction in this district as a result of their preparation and submission of NDA No. 203098 to the FDA.

FACTUAL BACKGROUND

A. The '894 Patent

21. On January 7, 2003, the '894 Patent was duly and legally issued to Unimed Pharmaceuticals, Inc., and Laboratoires Besins-Iscovesco as co-assignees of named inventors Robert E. Dudley, George S. Kottayil, Olivier Palatchi, and Dominique Drouin.[1] A true and correct copy of the '894 Patent is attached as Exhibit A to this Complaint.

22. In 2007, Unimed Pharmaceuticals, Inc. changed its name to Unimed Pharmaceuticals, LLC.

23. In 2004, Laboratoires Besins-Iscovesco changed its name to Besins-Iscovesco U.S., Inc. In 2008, Besins-Iscovesco U.S., Inc. changed its name to Besins Healthcare Inc.

24. The expiration date of the '894 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly

[1] A certificate of correction adding Dominique Drouin as an inventor was entered on May 22, 2007.

known as the "Orange Book") is August 30, 2020, with an extension for pediatric exclusivity until March 1, 2021.

B. AndroGel®

25. Abbott is the registered holder of approved NDA No. 21-015 for the manufacture and sale of testosterone gel, 1%, a prescription medicine used to treat adult males for conditions associated with a deficiency or absence of endogenous testosterone. Abbott markets and sells testosterone gel, 1% in the United States under the trade name AndroGel®. AndroGel® was approved by the FDA on February 28, 2000.

26. The '894 Patent is listed in the Orange Book in support of Abbott's AndroGel® (testosterone gel) 1%.

C. Infringement by Perrigo

27. On information and belief, Perrigo Company, acting on behalf of and as agent for Perrigo Israel, has submitted NDA No. 203098 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)) seeking approval to market Perrigo's Generic AndroGel®, prior to the expiration date of the '894 Patent. On information and belief, Perrigo Company and Perrigo Israel intend to engage in commercial manufacture, use, sale, offer for sale, or importation into the U.S. of Perrigo's Generic AndroGel® promptly upon receiving FDA approval to do so.

28. Plaintiffs received a letter dated September 20, 2011 (the "Notice Letter") signed on behalf of Perrigo Israel and identifying Perrigo Company as Perrigo Israel's agent, stating that the NDA includes a Paragraph IV Certification that, "in [Perrigo Israel's] opinion and to the best of its knowledge, the '894 Patent is invalid, unenforceable, and/or will not be

infringed by the commercial manufacture, use, sale or importation" of Perrigo's Generic AndroGel®.

29. On information and belief, the submission of NDA No. 203098 to the FDA constitutes infringement by Perrigo Company and Perrigo Israel of the '894 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Perrigo's Generic AndroGel® would infringe the '894 Patent under 35 U.S.C. § 271(a)–(c).

30. Plaintiffs commenced this action within 45 days of receiving the Notice Letter as required by 21 U.S.C. § 355(c)(3)(C).

CLAIMS FOR RELIEF

COUNT I
(PATENT INFRINGEMENT OF U.S. PATENT NO. 6,503,894)

31. Plaintiffs incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

32. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 203098 to the FDA seeking approval of Perrigo's Generic AndroGel® was an act of infringement of the '894 Patent by Defendants.

33. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '894 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT II
(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 6,503,894)

34. Plaintiffs incorporate by reference and reallege paragraphs 1 through 33 above as though fully restated herein.

35. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic AndroGel® prior to expiration of the '894 patent.

36. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic AndroGel® upon receipt of final FDA approval of NDA No. 203098, unless enjoined by the Court.

37. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic AndroGel® will constitute infringement of the '894 Patent under 35 U.S.C. § 271(a)–(c).

38. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic AndroGel® according to NDA No. 203098 will infringe one or more claims of the '894 Patent.

39. If Defendants' infringement of the '894 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a declaration that Defendants have infringed U.S. Patent No. 6,503,894;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by Defendants of the Proposed Gel will infringe U.S. Patent No. 6,503,894;

C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of NDA No. 203098 be no earlier than the expiration date of U.S. Patent No. 6,503,894, including any extensions or adjustments;

D. For an order enjoining Defendants and their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing U.S. Patent No. 6,503,894; and

E. For such other and further relief as this Court deems just and proper.

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.Civ.R. 11.2 that the matter in controversy is not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

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