IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs 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 Unimed Pharmaceuticals, LLC, which is a wholly-owned subsidiary of AbbVie Inc., is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

2. 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.

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

4. 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

5. 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 Abbreviated New Drug Application ("ANDA") No. 204268 submitted in the name of Perrigo Israel to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of AbbVie's AndroGel® (testosterone gel) 1.62% (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

6. 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.

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

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

PERSONAL JURISDICTION

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

10. As reported in its 2012 Annual Report on behalf of itself and its subsidiaries (collectively "Perrigo"), Perrigo operates as a "leading global provider" 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," which "markets a portfolio of generic prescription drug products for the U.S. market" that is focused on "topical dosage forms." On information and belief, Perrigo Israel, which is a wholly-owned subsidiary of Perrigo Company, is part of Perrigo's R_x Pharmaceuticals segment.

11. 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 Delaware, including at least Walgreens, Wal-Mart, CVS, and Rite Aid stores.

12. 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 Delaware, from which Perrigo Company derives substantial revenue.

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

14. 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 Annual Reports. On information and belief, Perrigo Israel derives substantial revenue from the sale of products to customers in Delaware.

15. 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. 04-107, 09-167, 09-758, and 10-592). Perrigo Company has further admitted to personal jurisdiction in this district (C.A. Nos. 09-758 and 10-592).

16. As further evidence of personal jurisdiction, Perrigo Israel has stipulated that it is subject to jurisdiction in the District of Delaware (C.A. No. 09-758 and 10-592).

17. On information and belief, Perrigo Israel, directly or in concert with related companies, has engaged in substantial and continuous contacts with Delaware which satisfy due process and confer personal jurisdiction over Perrigo Israel in Delaware on the basis of general jurisdiction.

18. 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 ANDA No. 204268. Perrigo Israel has represented that it submitted ANDA No. 204268 to the FDA through Perrigo Company, which acts as its authorized U.S. agent.

19. 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 ANDA No. 204268 to the FDA.

FACTUAL BACKGROUND

A. The ’894 Patent

20. On January 7, 2003, the ’894 Patent was duly and legally issued to Unimed Pharmaceuticals, Inc., and Laboratoires Besins-Iscovesco as co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the ’894 Patent is attached as Exhibit A to this Complaint.

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

22. 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.

23. Unimed Pharmaceuticals, LLC and Besins Healthcare Inc. are the owners of all right, title and interest in the ’894 patent.

24. The expiration date of the ’894 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the “Orange Book”) is August 30, 2020.

B. AndroGel®

25. AbbVie is the registered holder of approved NDA No. 22-309 for the manufacture and sale of testosterone gel, 1.62%, a prescription medicine used to treat adult males for conditions associated with a deficiency or absence of endogenous testosterone. AbbVie markets and sells testosterone gel, 1.62% in the United States under the trade name AndroGel®. AndroGel® 1.62% was approved by the FDA on April 29, 2011.

26. The ’894 Patent is listed in the Orange Book in conjunction with AndroGel® (testosterone gel) 1.62%, and the claims of the ’894 Patent cover that product.

C. Infringement by Perrigo

27. On information and belief, Perrigo Company, acting on behalf of and as agent for Perrigo Israel, has submitted ANDA No. 204268 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) 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 January 3, 2013 (the "Notice Letter") signed on behalf of Perrigo Israel and stating that ANDA No. 204268 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale or importation of Perrigo's Generic AndroGel® before the expiration of the '894 patent. The Notice Letter also states that, "Perrigo alleges, and has certified to FDA, that in Perrigo'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 ANDA No. 204268 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(j)(5)(B)(iii).

CLAIMS FOR RELIEF

COUNT I
(DIRECT 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 ANDA No. 204268 to the FDA seeking approval of Perrigo's Generic AndroGel® was an act of infringement of the '894 Patent by Defendants.

33. If allowed on the market, Perrigo's Generic AndroGel® will infringe the '894 Patent under 35 U.S.C. § 271(a).

34. 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.

35. Defendants' infringement of the '894 Patent is willful and made with knowledge of the '894 Patent.

COUNT II
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 6,503,894)

36. Plaintiffs incorporate by reference and reallege paragraphs 1 through 35 above as though fully restated herein.

37. Defendants have knowledge of the '894 Patent.

38. Upon FDA approval of ANDA No. 204268, Defendants will intentionally encourage acts of direct infringement of the '894 Patent by others, with knowledge that their acts are encouraging infringement.

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

39. Plaintiffs incorporate by reference and reallege paragraphs 1 through 38 above as though fully restated herein.

40. If ANDA No. 204268 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic AndroGel®.

41. On information and belief, Defendants have had and continue to have knowledge that Perrigo's Generic AndroGel® is especially adapted for a use that infringes the '894 patent.

42. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic AndroGel®.

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

43. Plaintiffs incorporate by reference and reallege paragraphs 1 through 42 above as though fully restated herein.

44. 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.

45. 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 ANDA No. 204268, unless enjoined by the Court.

46. 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).

47. 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 ANDA No. 204268 will infringe one or more claims of the '894 Patent.

48. 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 Perrigo's Generic AndroGel® 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 ANDA No. 204268 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;

E. For a determination that this is an exceptional case under 35 U.S.C. § 285; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

Mary B. Graham (#2256)
Paul C. Saindon (#5110)
Stephen J. Kraftschik (#5623)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
psaindon@mnat.com
skraftschik@mnat.com
Attorneys for Unimed Pharmaceuticals, LLC and Besins Healthcare Inc.

OF COUNSEL:

Calvin P. Griffith
Jason G. Winchester
Gasper LaRosa
Marron Mahoney
JONES DAY
North Point
901 Lakeside Ave.
Cleveland, OH 44114
Attorneys for Unimed Pharmaceuticals, LLC

Stephen A. Bent
FOLEY & LARDNER LLP
3000 K Street, N.W., Suite 600
Washington, DC 20007-5109

Debra D. Nye
FOLEY & LARDNER LLP
3579 Valley Centre Drive, Suite 300
San Diego, CA 92130-3302
Attorneys for Besins Healthcare Inc.

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