IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC and BESINS HEALTHCARE INC.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
WATSON LABORATORIES, INC. and ACTAVIS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Unimed Pharmaceuticals, LLC ("Unimed"), and Besins Healthcare Inc. ("Besins") allege as follows for their complaint against Defendants Watson Laboratories, Inc. ("Watson Laboratories") and Actavis, Inc. (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 Actavis, Inc. was formerly known as Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") until on or around January 24, 2013. Actavis, Inc. is a corporation organized and existing under the laws of the State of

Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. On information and belief, Defendant Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada with its principal place of business at 311 Bonnie Circle, Corona, California 92880.

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. 204570 submitted in the name of Watson Laboratories to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of AbbVie's AndroGel® (testosterone gel) 1.62% (Watson'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 Defendants' 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 "Actavis"), Actavis operates as "a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of," *inter alia*, generic, branded generic, and brand pharmaceutical products. As described in that Annual Report, one of Actavis's business segments is "Actavis Pharma," formerly known as Watson Pharmaceuticals's "Global Generics" segment, which markets a "U.S. portfolio of approximately 250 generic pharmaceutical product families." On information and belief, Watson Laboratories, which is a wholly-owned subsidiary of Actavis, Inc., is part of Actavis's "Actavis Pharma" segment.

11. According to Actavis's 2012 Annual Report, "efforts are underway to change the underlying 'Watson' subsidiary and legal entity names to an 'Actavis' name."

12. According to Actavis's 2012 Annual Report, Actavis sells its "generic and brand pharmaceutical products primarily to drug wholesalers, retailers and distributors, including national retail drug and food store chains" such as Walgreens. On information and belief, Actavis, Inc., directly or through related companies, intends to sell Watson's Generic AndroGel® through these same retail outlets in Delaware, including at least Walgreens.

13. On information and belief, Actavis, Inc. and Watson Laboratories share common officers and directors.

14. On information and belief, Watson Laboratories is within the control of Actavis, Inc. for purposes of responding to discovery in this action.

15. On information and belief, Actavis, Inc. has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other entities, Watson Laboratories.

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

17. On information and belief, Actavis, Inc. directs the activities of the other Actavis entities, including Watson Laboratories, and, directly or through related companies, is responsible for sales of Actavis products to customers in Delaware, from which Actavis, Inc. derives substantial revenue.

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

19. On information and belief, Watson Laboratories develops and manufactures pharmaceutical products for the United States market for Actavis, and has developed and manufactured such products which are available at pharmacies or elsewhere in the United States, including Delaware. On information and belief, Watson Laboratories derives substantial revenue from the sale of products to customers in Delaware.

20. On information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available in retail pharmacies in Delaware.

21. As further evidence of personal jurisdiction over Actavis, Inc., Actavis, Inc., as Watson Pharmaceuticals, has been sued for patent infringement in this district and has not contested personal jurisdiction. (*See, e.g.*, C.A. Nos. 12-258, 12-1124, and 12-1726). Actavis, Inc., as Watson Pharmaceuticals, further has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. (*See, e.g.*, C.A. No. 12-993).

22. As further evidence of personal jurisdiction over Watson Laboratories, in *Cephalon Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009), this Court found general personal jurisdiction over Watson Laboratories due to its extensive contacts with Delaware. Additionally, Watson Laboratories has been sued for patent infringement in this district and has not contested personal jurisdiction. (*See, e.g.*, C.A. Nos. 12-258, 12-1124, and 12-1726). Watson Laboratories further has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. (*See, e.g.*, C.A. Nos. 12-258, 12-1124, and 12-1726).

23. On information and belief, and consistent with their practice with respect to other generic products, Actavis, Inc. and Watson Laboratories acted in concert to prepare and submit ANDA No. 204570. For example, by letter dated February 11, 2013 ("Notice Letter"), Watson Laboratories directed Plaintiffs to send any written notice regarding confidential access to Watson Laboratories's ANDA to Kenton M. Walker, who is Senior Counsel, Intellectual Property for Actavis.

24. On information and belief, Actavis, Inc. and Watson Laboratories are subject to specific personal jurisdiction in this district as a result of their preparation and submission of ANDA No. 204570 to the FDA.

FACTUAL BACKGROUND

A. The ’894 Patent

25. 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.

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

27. 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.

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

29. 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®

30. 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.

31. 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 Defendants

32. On information and belief Watson Laboratories, acting on behalf of and as agent for Actavis, Inc., has submitted ANDA No. 204570 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to market Watson's Generic AndroGel®, prior to the expiration date of the '894 Patent. On information and belief, Defendants intend to engage in commercial manufacture, use, sale, offer for sale, or importation into the U.S. of Watson's Generic AndroGel® promptly upon receiving FDA approval to do so.

33. On February 12, 2013, Plaintiffs received a Notice Letter dated February 11, 2013, signed on behalf of Watson Laboratories and stating that ANDA No. 204570 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale or importation of Watson's Generic AndroGel® before the expiration of the '894 Patent. The Notice Letter also states that, "Watson certifies, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that in its 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, or sale of Watson's product bioequivalent to Androgel® 1.62% Testosterone Gel before the expiration date of this patent."

34. On information and belief, the submission of ANDA No. 204570 to the FDA constitutes infringement by Defendants of the '894 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Watson's Generic AndroGel® would infringe the '894 Patent under 35 U.S.C. § 271(a)–(c).

35. 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)

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

37. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204570 to the FDA seeking approval of Watson's Generic AndroGel® was an act of infringement of the '894 Patent by Defendants.

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

39. 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.

40. 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)

41. Plaintiffs incorporate by reference and reallege paragraphs 1 through 40 above as though fully restated herein.

42. Defendants have knowledge of the '894 Patent.

43. Upon FDA approval of ANDA No. 204570, 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)

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

45. If ANDA No. 204570 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Watson's Generic AndroGel®.

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

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

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

48. Plaintiffs incorporate by reference and reallege paragraphs 1 through 47 above as though fully restated herein.

49. 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 Watson's Generic AndroGel® prior to expiration of the '894 Patent.

50. 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 Watson's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 204570, unless enjoined by the Court.

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

52. 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 Watson's Generic AndroGel® according to ANDA No. 204570 will infringe one or more claims of the '894 Patent.

53. 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 Watson'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. 204570 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

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