IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT PRODUCTS, INC., UNIMED PHARMACEUTICALS, LLC, and BESINS HEALTHCARE INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Abbott Products, Inc. ("Abbott"), Unimed Pharmaceuticals, LLC ("Unimed"), and Besins Healthcare Inc. ("Besins") (collectively, "Plaintiffs") state the following as their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"):

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, 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. Unimed Pharmaceuticals, LLC, is a wholly-owned subsidiary of Abbott Products, Inc. Abbott Products, Inc., formerly known as Solvay Pharmaceuticals, Inc., is a wholly-owned subsidiary of Abbott Products US Holdings, Inc., formerly known as Solvay Pharma U.S. Holdings, Inc. Abbott Products US Holdings, Inc., is a Delaware corporation.

Abbott Laboratories, an Illinois corporation, is the current ultimate parent corporation of Abbott Products US Holdings, Inc.

4. 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.

5. Plaintiffs are informed and believe, and thereupon allege, that Defendant Teva Pharmaceuticals USA, Inc., is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

6. Plaintiffs are informed and believe, and thereupon allege, that, unless specifically stated otherwise, the acts complained of herein were committed by, on behalf of, and/or for the benefit of Teva.

NATURE OF THE ACTION

7. This is an action for patent infringement. This action relates to New Drug Application ("NDA") No. 202-763 filed by Teva with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Abbott's AndroGel® (testosterone gel) 1%.

8. Plaintiffs are informed and believe, and thereupon allege, that Teva has been infringing, is infringing, or will infringe one or more claims of U.S. Patent No. 6,503,894 (the "'894 Patent").

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Teva because Teva is a company organized under the laws of Delaware, conducts business in this district, and purposefully avails itself of the rights and benefits of Delaware law.

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

FACTUAL BACKGROUND

A. The '894 Patent

12. On January 7, 2003, U.S. Patent No. 6,503,894, titled "Pharmaceutical Composition and Method for Treating Hypogonadism," 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.

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

14. 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.

15. 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, with an extension for pediatric exclusivity until March 1, 2021.

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

B. AndroGel®

16. 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.

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

C. Infringement by Teva

18. Plaintiffs are informed and believe, and thereupon allege, that Teva has submitted NDA No. 202-763 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). The NDA seeks approval to market testosterone gel 1% (the "Proposed Gel") as a generic version of AndroGel®, prior to the expiration date of the '894 Patent. Plaintiffs further are informed and believe, and thereupon allege, that Teva intends to engage in commercial manufacture, use, sale, offer to sell, or importation into the U.S. of the Proposed Gel promptly upon receiving FDA approval to do so.

19. On March 17, 2011, Plaintiffs received a letter dated March 16, 2011 (the "Notice Letter") from Teva, stating that the NDA includes a Paragraph IV Certification that, in Teva's opinion, the '894 Patent will not be infringed by the manufacture, use, sale, offer to sell, or importation into the U.S. of the Proposed Gel.

20. Plaintiffs are informed and believe, and thereupon allege, that the NDA does not provide any valid basis for concluding that the '894 Patent will not be infringed by the commercial manufacture, use, or sale of the Proposed Gel.

21. Plaintiffs are informed and believe, and thereupon allege, that the submission of the NDA to the FDA constitutes infringement of the '894 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, or import of the Proposed Gel would infringe the '894 Patent under 35 U.S.C. § 271(a)–(c).

22. 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)

23. Plaintiffs incorporate by reference and reallege paragraphs 1 through 22 above as though fully restated herein.

24. Pursuant to 35 U.S.C. § 271(e)(2), Teva's submission of NDA No. 202-763 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Gel was an act of infringement of the '894 Patent.

25. Unless Teva is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Teva's 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)

26. Plaintiffs incorporate by reference and reallege paragraphs 1 through 25 above as though fully restated herein.

27. Plaintiffs are informed and believe, and thereupon allege, that Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Proposed Gel prior to patent expiry.

28. Plaintiffs are informed and believe, and thereupon allege, that Teva intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Gel upon receipt of final FDA approval of NDA No. 202-763.

29. Pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Teva's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Gel will constitute infringement of the '894 Patent.

30. Teva's infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Gel complained of herein will begin following FDA approval of NDA No. 202-763.

31. Plaintiffs are informed and believe, and thereupon allege, that Teva maintains, and Plaintiffs deny, that the '894 Patent will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Proposed Gel. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and Teva regarding whether Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the Proposed Gel according to NDA No. 202-763 will infringe one or more claims of the '894 Patent. Plaintiffs thus are entitled to a declaration that the making, using, sale, offer for sale, and importation into the United States of the Proposed Gel according to NDA No. 202-763 infringe one or more claims of the '894 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

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

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation by Teva of the Proposed Gel would 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. 202-763 be no earlier than the expiration date of U.S. Patent No. 6,503,894, including any extensions or adjustments;

D. For an order preliminarily and permanently enjoining Teva and its 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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