

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No.

AUXILIUM PHARMACEUTICALS, INC. and
CPEX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

UPSHER-SMITH LABORATORIES, INC.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Auxilium Pharmaceuticals, Inc. and CPEX Pharmaceuticals, Inc. for their complaint against Defendant Upsher-Smith Laboratories, Inc. hereby state as follows:

THE PARTIES

1. Auxilium Pharmaceuticals, Inc. ("Auxilium") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Auxilium is a specialty biopharmaceutical company with a focus on developing and marketing pharmaceutical products to urologists, endocrinologists, orthopedists and select primary care physicians. Auxilium is in the business of developing and marketing a variety of pharmaceutical products that focus on novel treatment options for patient populations with unmet medical needs.

2. CPEX Pharmaceuticals, Inc. ("CPEX") is a Delaware corporation with its principal place of business in Exeter, New Hampshire. CPEX is a specialty

pharmaceutical company in the business of development, licensing and commercialization of pharmaceutical products utilizing its validated drug delivery technology.

3. Auxilium is the holder of approved New Drug Application 21-454 for a transdermal testosterone gel, which has the proprietary name Testim[®] and is sold by Auxilium throughout the United States, Europe, and Canada. Testim[®] has been approved by the United States Food and Drug Administration (“FDA”) for the treatment of hypogonadism in men, which is a medical condition that occurs when the body does not make enough testosterone.

4. Upon information and belief, Upsher-Smith Laboratories, Inc. (“Upsher-Smith”) is a company organized and existing under the laws of Minnesota with a place of business at 301 S. Cherokee Street, Denver, Colorado 80223. Upon information and belief, Defendant Upsher-Smith manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, et seq., and in particular under 35 U.S.C. § 271(e). This action relates to an Abbreviated New Drug Application (“ANDA”) filed by Upsher-Smith with the FDA for approval to market a copy of Auxilium’s highly successful Testim[®] transdermal testosterone gel.

JURISDICTION AND VENUE

6. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Upsher-Smith by virtue of the fact that, *inter alia*, Upsher-Smith has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Auxilium and CPEX. Upon information and belief, this Court has personal jurisdiction over Upsher-Smith for the additional reasons set forth below and for other reasons that will be presented to the Court, if such jurisdiction is challenged.

8. Upon information and belief, Upsher-Smith has a manufacturing facility located in Denver, Colorado and employs personnel in the State. Also, upon information and belief, Upsher-Smith manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. Further, upon information and belief, this Court has personal jurisdiction over Upsher-Smith by virtue of, *inter alia*, its systematic and continuous contacts with Colorado, including the substantial revenue it derives from the State of Colorado through the sale and consumption of its pharmaceutical products within the State of Colorado.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

BACKGROUND

10. United States Patent No. 7,320,968 (“the '968 Patent”), entitled “Pharmaceutical Composition,” was duly and legally issued by the United States Patent and Trademark Office on January 22, 2008. The term of the '968 Patent expires in January 2025. A true and correct copy of the '968 Patent is attached as Exhibit A.

11. CPEX is the lawful owner by assignment of the '968 Patent and has the right to sue for infringement of the '968 Patent.

12. In May 2000, Auxilium and CPEX's predecessor-in-interest, Bentley Pharmaceuticals, Inc. ("Bentley"), entered into a License Agreement ("License Agreement") whereby, *inter alia*, Auxilium was granted (a) an exclusive world-wide license to U.S. Serial No. 10/473,724 (which issued as the '968 Patent) and to any and all continuations, continuations-in-part, additions, divisions, renewals, extensions, re-examinations and reissues thereof, including any and all foreign counterparts; and (b) the right to sue for infringement of the '968 Patent.

13. In 2008, CPEX was spun out of Bentley and CPEX became the owner of the '968 Patent and related patent applications, as well as the licensor under the aforementioned License Agreement.

14. Auxilium has listed the '968 Patent in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) published by the FDA, as covering methods of treatment using its Testim[®] transdermal testosterone gel.

15. Upon information and belief, Upsher-Smith has filed with the FDA Abbreviated New Drug Application 79-178 ("the Upsher-Smith ANDA") under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, and sale of a testosterone transdermal gel product in a 1% strength. Upon information and belief, Upsher-Smith filed its ANDA No. 79-178 to obtain approval to market a generic form of

Auxilium's Testim[®] testosterone transdermal gel, before the expiration of the '968 Patent.

16. On behalf of Upsher-Smith, Sean B. Mahoney, counsel for Upsher-Smith, sent a letter dated October 22, 2008, to Auxilium and Bentley, to provide notice, pursuant to 21 U.S.C. § 355 (j)(2)(B), that Upsher-Smith had filed ANDA 79-178 with respect to testosterone transdermal gel in a 1% strength. The letter further provided notice that Upsher-Smith had filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv), a certification ("Paragraph IV certification") alleging that U.S. Patent No. 7,320,968 is not infringed. The letter also included a statement of factual and legal allegations upon which Upsher-Smith based its certifications to the FDA.

**UPSHER-SMITH'S FAILURE TO COMPLY WITH
21 U.S.C. § 355(j) CONFIDENTIAL ACCESS REQUIREMENTS**

17. In its Paragraph IV certification, Upsher-Smith offered Auxilium and Bentley (now CPEX) confidential access ("OCA") to unidentified portions of its ANDA for the sole and limited purpose of determining whether an infringement action could be brought against Upsher-Smith within the 45-day window provided by the statutory scheme set forth in 21 U.S.C. § 355(j), et seq. However, Upsher-Smith's OCA set forth a number of onerous and unreasonable conditions and limitations on what individuals could have access to Upsher-Smith's ANDA and the information or data contained therein.

18. Over the course of the next few weeks and within the 45-day window which Auxilium and CPEX had under the statutory scheme set forth in 21 U.S.C. § 355(j), counsel for Auxilium and CPEX had several communications with Upsher-

Smith's counsel in an effort to modify the conditions of access set out in Upsher-Smith's OCA. More specifically, counsel for Auxilium and CPEX requested elimination of restrictions in Upsher-Smith's OCA that would have substantially impaired their ability to effectively communicate with a single management designee of Auxilium and CPEX regarding their evaluation of Upsher-Smith's assertions in its Paragraph IV certification, which would have been further informed by an evaluation of Upsher-Smith's ANDA. In addition, counsel for Auxilium and CPEX sought to modify the restrictions on access by outside experts in Upsher-Smith's proposed OCA since the conditions proposed by Upsher-Smith would substantially impair Auxilium's and CPEX's ability to retain qualified experts in the field of transdermal delivery to assist in the evaluation of Upsher-Smith's ANDA.

19. In an effort to strike a reasonable balance between preventing the potential for misuse of Upsher-Smith's confidential information in its ANDA and eliminating insuperable conditions on access by CPEX and Auxilium, counsel for Auxilium and CPEX proposed a number of reasonable conditions to modify Upsher-Smith's proposed OCA. Although Upsher-Smith agreed to some modification to its original OCA, Upsher-Smith ultimately did not agree to remove conditions that would impair Auxilium's and CPEX's ability to retain qualified experts in the field of transdermal delivery to assist in the evaluation of Upsher-Smith's ANDA.

20. Upsher-Smith's offer of confidential access to its ANDA did not meet the requirements of 21 U.S.C. § 355(j).

COUNT ONE: INFRINGEMENT OF UNITED STATES PATENT NO. 7,320,968

21. The allegations of the preceding paragraphs 1-20 are repeated, realleged, and incorporated herein by reference.

22. Upsher-Smith's Paragraph IV certification alleged that its testosterone transdermal gel product in ANDA No. 79-178 will not infringe claims 1-4 of the '968 Patent.

23. Under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to the FDA of ANDA No. 79-178 to obtain approval for the commercial manufacture, use, or sale of its testosterone transdermal gel product before the expiration of the '968 Patent constitutes infringement of the '968 Patent.

24. Upon FDA approval of ANDA No. 79-178 and upon information and belief, Upsher-Smith will infringe the '968 Patent by making, using, offering to sell, selling, and/or importing the testosterone transdermal gel product in the United States, and/or by actively inducing and/or by contributing to infringement by others under 35 U.S.C. § 271, unless this Court orders that the effective date of any FDA approval of Upsher-Smith's ANDA shall be no earlier than the expiration date of the '968 Patent.

25. Upon information and belief, Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 constitutes a material part of at least one of the claims of the '968 Patent; Upsher-Smith knows that its testosterone transdermal gel product is especially made or adapted for use in a manner infringing at least one of the claims of the '968 Patent; and Upsher-Smith's testosterone transdermal gel product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

26. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 would contributorily infringe at least one of the claims of the '968 Patent.

27. Upon information and belief, Upsher-Smith had knowledge of the '968 Patent and, by its promotional activities and package insert for its testosterone transdermal gel product in ANDA No. 79-178, Upsher-Smith knows or should know that it will actively aid and abet another's infringement of at least one of the claims of the '968 Patent.

28. Upon information and belief, the offer to sell, sale, and/or importation of Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 would actively induce infringement of at least one of the claims of the '968 Patent.

29. Auxilium and CPEX will be substantially and irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Auxilium and CPEX have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Auxilium and CPEX respectfully request that this Court enter judgment in their favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Upsher-Smith's submission to the FDA of ANDA No. 79-178 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Upsher-Smith's testosterone transdermal gel product before the expiration of the '968 Patent was an act of infringement of the '968 Patent;

(2) declaring that Upsher-Smith's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 would constitute infringement of the '968 Patent;

(3) ordering that the effective date of any FDA approval of Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 shall be no earlier than the expiration of the '968 Patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(4) enjoining Upsher-Smith and all persons and entities acting in concert with Upsher-Smith from commercially manufacturing, using, offering for sale, or selling Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 within the United States, or importing Upsher-Smith's testosterone transdermal gel product in ANDA No. 79-178 into the United States, until the expiration of the '968 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(5) awarding Auxilium and CPEX their costs and expenses in this action; and

(6) awarding Auxilium and CPEX any further and additional relief as this Court deems just and proper.

Dated December 5, 2008

s/ Peter J. Korneffel

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