IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUMBERLAND PHARMACEUTICALS INC., Plaintiff, v. AKORN, INC., Defendant.	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Cumberland Pharmaceuticals Inc. (hereinafter "Cumberland"), brings this Complaint for patent infringement against Akorn, Inc. (hereinafter "Akorn"). This action concerns a patent related to Cumberland's product Acetadote®, an intravenous formulation of N-acetylcysteine, widely used to treat suspected acetaminophen overdose to prevent or lessen hepatic injury.

Parties

l. Cumberland is a Tennessee corporation having its corporate offices and principal place of business at 2525 West End Ave., Suite 950, Nashville, TN 37203. Cumberland is engaged in the business of development, manufacture, and sale of pharmaceutical products.

2. On information and belief, Akorn is a Louisiana corporation having its corporate offices and a principal place of business at 1925 West Field Court, Suite 300, Lake Forest, IL 60045. On information and belief, Akorn is engaged in the development, manufacture, marketing, and distribution of generic pharmaceutical products for sale throughout the United States.

Jurisdiction and Venue

3. This is a complaint for patent infringement and for declaratory judgment of patent infringement. The jurisdiction of this Court is properly founded under 28 U.S.C. §§ 1331 and 1338(a) as well as 28 U.S.C. §§ 2201 and 2202.

4. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

5. Akorn is subject to personal jurisdiction in this Court because, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the regular marketing and sale of pharmaceutical products within the State of Delaware. Among other things, on information and belief, Akorn, Inc. has entered into contracts with Delaware companies, including at least Amerisource Bergen and McKesson. On information and belief, Akorn has registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DS0270) and "Pharmacy-Wholesale" (License Nos. A4-0000687 and A4-0000573). Moreover, on information and belief, Akorn wholly owns three subsidiaries that are incorporated in Delaware (Advanced Vision Research, Inc., Akorn Ophthalmics, Inc., and Oak Pharmaceuticals, Inc.) and is a 50% owner of a Delaware joint venture (Akorn-Strides, LLC).

Claim for Relief

6. Cumberland is the owner of U.S. Patent No. 8,148,356 ("the '356 patent"), entitled "Acetylcysteine Composition and Uses Therefor" (attached as Exhibit A), a valid patent, duly and legally issued on April 3, 2012.

7. A commercial embodiment encompassed by the patent-in-suit is a formulation of N-acetylcysteine ("acetylcysteine") currently sold by Cumberland pursuant to New Drug

Application (" NDA") No. 021539 under the trademark Acetadote®. Cumberland is the holder of NDA No. 021539 for Acetadote®.

8. Acetadote® is an intravenous formulation of N-acetylcysteine. Acetadote® is currently used in hospital emergency departments to prevent or lessen potential liver damage resulting from suspected overdose of acetaminophen. Acetaminophen overdose continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States, and Acetadote® has become a standard of care for treating this potentially life-threatening condition.

15. On information and belief, Akorn has filed Abbreviated New Drug Application ("ANDA") No. 203173 with the FDA seeking approval to market a generic Acetadote® formulation, which contains a certification under 21 U.S.C. § 355(j)(2)(B)(i) and (ii) ("Paragraph IV" Certification) that the '356 patent is invalid and/or not infringed.

The Infringing Conduct by Defendant

Count I - Patent Infringement of the '356 Patent

16. Cumberland realleges and incorporates by reference paragraphs 1-15.

17. By submitting its ANDA and Paragraph IV Certification under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, or importation of its acetylcysteine formulation before the expiration of the '356 patent, Akorn infringed one or more claims of the '356 patent under 35 U.S.C. § 271(e)(2).

18. Akorn has knowledge of the '356 patent, and Akorn's actions constitute knowing and willful infringement of the valid '356 patent.

19. As a result of Akorn's infringement of the '356 patent, Cumberland has been and will continue to be damaged unless said infringement is enjoined by this Court. Cumberland

presently has no adequate remedy of law.

Count II - Declaratory Judgment of Infringement of the ’356 Patent

20. Cumberland realleges and incorporates by reference paragraphs 1-19.

21. Akorn has filed or caused to be filed an application with the FDA, seeking authorization to import, market, use, and sell its proposed acetylcysteine formulation for one or more indications before the expiration of the ’356 patent. Akorn had knowledge of the ’356 patent at least as of May 31, 2013.

22. On information and belief, Akorn is expecting approval of its ANDA.

23. On information and belief, Akorn plans to begin marketing, selling, and offering to sell its acetylcysteine formulation drug product soon after FDA approval.

24. Such conduct will constitute infringement of one or more claims of the ’356 patent under 35 U.S.C. § 271(a). By manufacturing, offering for sale or selling its proposed acetylcysteine formulation directly or indirectly to hospitals or other emergency care facilities, Akorn will knowingly induce medical care providers to infringe the ’356 patent under 35 U.S.C. § 271(b).

25. Akorn’s infringing activity complained of herein is imminent and will begin following FDA approval of its application seeking one or more acetylcysteine indications.

26. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cumberland and Akorn as to liability for the infringement of the ’356 patent. Akorn’s actions constitute a knowing and willful infringement of the ’356 patent. Akorn’s actions have created in Cumberland’s mind a reasonable apprehension of irreparable harm and loss resulting from Akorn’s threatened imminent actions.

Relief Requested

Wherefore, Cumberland prays for judgment and relief including:

(A) A declaration that United States Patent No. 8,148,356 is valid and enforceable;

(B) A declaration that Akorn's submission of ANDA No. 203173 constitutes an act of infringement of one or more claims of the '356 patent under § 271(e)(2);

(C) A declaration that Akorn will infringe one or more claims of the '356 patent by importing, using, offering to sell, and selling its acetylcysteine formulation drug product prior to expiration of the '356 patent;

(D) A declaration that the effective date of any approval of Akorn's acetylcysteine formulation drug product is not to be earlier than the expiration of the '356 patent under 35 U.S.C. § 271(e)(4)(A);

(E) A declaration that Akorn has no legal or equitable defense to Cumberland's allegations of infringement.

(F) A preliminary and permanent injunction pursuant to 35 U.S.C. § 283, enjoining Akorn and its officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the '356 patent under 35 U.S.C. § 271(e)(4)(B).

(G) An accounting and award of damages incurred by Cumberland as a result of Akorn's infringement if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States under 35 U.S.C. § 271(e)(4)(C).

(H) An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Cumberland its attorneys' fees in pursuing this case and reasonable costs and expenses incurred in this case; and

(I) Such further and other relief as this Court may deem just and proper.

Date: July 12, 2013

/s/ Kristen Healey Cramer
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