IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUMBERLAND PHARMACEUTICALS INC., Plaintiff, v. PADDOCK LABORATORIES, LLC, and PERRIGO COMPANY, Defendants.	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Cumberland Pharmaceuticals Inc. (hereinafter "Cumberland"), brings this Complaint for patent infringement against Paddock Laboratories, LLC ("Paddock"), and Perrigo Company ("Perrigo"). 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

1. 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, Paddock is a Delaware corporation having its corporate offices and a principal place of business at 3940 Quebec Avenue N, Minneapolis, MN 55427. On information and belief, Paddock is engaged in the development, manufacture, marketing, and distribution of generic pharmaceutical products for sale throughout the United

States.

3. On information and belief, Perrigo now owns the assets of Paddock. Perrigo is a Michigan corporation having its corporate offices and a principal place of business at 515 Eastern Avenue, Allergan MI 49010. Upon information and belief Perrigo is a large and diverse drug manufacturing and sales company that distributes and sells its products throughout the United States, including substantial sales in the State of Delaware.

Jurisdiction and Venue

4. 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.

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

6. Paddock is incorporated in Delaware and is thus subject to the personal jurisdiction of this Court.

7. Perrigo distributes and sells its products throughout the United States, including substantial sales in the State of Delaware. Paddock filed its Abbreviated New Drug Application ("ANDA") for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B)(ii)—the acts which give rise to the instant litigation—with knowledge that Cumberland would be injured by such actions in Delaware. On information and belief, Perrigo now has ownership rights in and control over Paddock's ANDA

8. On information and belief, Perrigo has maintained continuous and systematic contacts with Delaware and has purposefully availed itself of the privileges of doing business under the laws of Delaware. Thus, Perrigo is subject to personal jurisdiction in this judicial district.

Claim for Relief

9. 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.

10. 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®.

11. 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.

12. When it was originally approved by the U.S. Food and Drug Administration ("FDA") in 2004, Cumberland's initial Acetadote® formulation included an inactive ingredient, ethylene diamine tetraacetic acid ("EDTA") ("Cumberland's discontinued formulation"). In Cumberland's discontinued formulation, EDTA served as a chelating agent, which bonds with and thereby sequesters free metal ions from solution. Due to safety concerns regarding the use of EDTA, the FDA conditioned its approval of Acetadote® on Cumberland's commitment to conduct post-launch studies to investigate whether a commercially viable formulation of Acetadote® could be made with reduced amounts, or no amount, of EDTA.

13. EDTA can cause side effects such as significant drops in serum calcium levels, which may result in fatality, hypokalemia, hypomagnesemia, or hypotension. (*See* '356 patent,

col. 2, ll. 12-35.) In addition, some individuals are allergic to EDTA such that they cannot receive acetylcysteine compositions containing EDTA or may require additional care after receiving such compositions. (*Id.*) Pharmaceutical manufacturers have removed EDTA from injectables, for example Leukine® and Nesacain-MPF, in light of adverse events associated with EDTA. (*See, e.g.*, U.S. Food and Drug Administration, *Safety: Leukine (sargramostim)*, Jan. 23, 2008, http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm090918.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=bayer; Eugene E. Fibuch & Susan E. Opper, *Back Pain Following Epidurally Administered Nesacaine-MPF*, 69 ANESTH. ANALG. 113-115 (1989).)

14. Cumberland conducted an investigation into whether or not it was possible to modify Acetadote® to address the FDA's safety concerns. At the time, the state of the art continued to teach away from removing EDTA, which was thought to be required.

15. Contrary to the expectations and teaching in the field, Cumberland was successful in developing a new formulation that contained no EDTA or any other chelating agent yet offered surprisingly good stability.

16. In September 2010, Cumberland submitted a supplemental new drug application (sNDA) to the FDA for approval of this new formulation of Acetadote® designed to replace the original formulation.

17. In January 2011, Cumberland received FDA approval for this new Acetadote® formulation ("Cumberland's current formulation") and ceased marketing Cumberland's discontinued formulation. Cumberland no longer manufactures the discontinued formulation.

18. On information and belief, Paddock has filed ANDA No. 200513 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, unenforceable, and/or not infringed.

19. On information and belief, Paddock's proposed acetylcysteine product contains EDTA. 21 C.F.R. § 314.127(a)(8)(ii)(A) provides, inter alia, that the "FDA will refuse to approve an abbreviated application for a new drug under section 505(j) of the act . . . if, on the basis of information available to the agency, there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raises serious questions of safety or efficacy." FDA approval as safe and effective of a generic Acetadote® formulation that contains EDTA would be contrary to FDA regulations, particularly where, as here, there is available a safer and at least equally effective alternative EDTA-free formulation, i.e., Cumberland's current formulation.

The Infringing Conduct by Defendants

Count I - Patent Infringement of the '356 Patent

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

21. By submitting an 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, Paddock and Perrigo infringed one or more claims of the '356 patent under 35 U.S.C. § 271(e)(2).

22. Paddock and Perrigo have knowledge of the '356 patent, and their actions constitute knowing and willful infringement of the valid '356 patent.

23. As a result of Paddock's and Perrigo'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

24. Cumberland realleges and incorporates by reference paragraphs 1-23.

25. Paddock 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. Paddock had knowledge of the '356 patent at least as of April 4, 2012.

26. On information and belief, Paddock is expecting approval of its ANDA.

27. On information and belief, Paddock and Perrigo plan to begin marketing, selling, and offering to sell its acetylcysteine formulation drug product soon after FDA approval.

28. 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, Paddock and Perrigo will knowingly induce medical care providers to infringe the '356 patent under 35 U.S.C. § 271(b).

29. Paddock's and Perrigo's infringing activity complained of herein is imminent and will begin following FDA approval of its application seeking one or more acetylcysteine indications.

30. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cumberland on the one hand and Paddock and Perrigo on the other as to liability for the infringement of the '356 patent. Paddock's and Perrigo's actions constitute a knowing and willful infringement of the '356 patent. Paddock's and Perrigo's

actions have created in Cumberland's mind a reasonable apprehension of irreparable harm and loss resulting from Paddock's and Perrigo'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 Paddock's submission of ANDA No. 200513 constitutes an act of infringement of one or more claims of the '356 patent under § 271(e)(2);

(C) A declaration that Paddock and Perrigo 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 Paddock'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 Paddock and Perrigo have 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 Paddock and Perrigo and their 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 Paddock's and Perrigo'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: May 17, 2012

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