IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUMBERLAND PHARMACEUTICALS INC., Plaintiff, v. SAGENT AGILA LLC, and SAGENT PHARMACEUTICALS, INC., Defendants.	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Cumberland Pharmaceuticals Inc. (hereinafter "Cumberland"), brings this Complaint for patent infringement against Sagent Agila LLC, and Sagent Pharmaceuticals, Inc. (collectively "Defendants"). 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. Plaintiff 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. Defendant Sagent Pharmaceuticals, Inc. is a Delaware corporation having its corporate offices and a principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, IL 60195-3194. Upon information and belief, Sagent Pharmaceuticals, Inc.

develops, manufactures, sources, and markets pharmaceutical products throughout the United States, including the State of Delaware.

3. On information and belief, defendant Sagent Agila LLC is a Wyoming corporation having its corporate offices and a principal place of business at 2120 Carey Ave Ste. 300, Cheyenne, WY 82001. Sagent Agila LLC (formerly Sagent Strides LLC) is a 50/50 joint venture formed between defendant Sagent Pharmaceuticals, Inc. and Strides Acrolab Limited. On information and belief, Sagent Agila LLC was formed for the purpose of developing, supplying, and selling into the U.S. market generic injectable products in cooperation with defendant Sagent Pharmaceuticals, Inc., including the State of Delaware.

4. On information and belief, the acts of defendant Sagent Agila LLC at issue in this Complaint were committed at the direction of, and/or with the authorization of, cooperation, participation, and assistance of, and at least in part for the benefit of, defendant Sagent Pharmaceuticals, Inc.

Jurisdiction and Venue

5. 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.

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

7. On information and belief, defendant Sagent Pharmaceuticals, Inc. is a Delaware corporation and is subject to the jurisdiction of this Court for at least this reason.

8. On information and belief, this Court has personal jurisdiction over defendant Sagent Agila LLC by virtue of its continuous and systematic contacts with this forum, including, *inter alia*, marketing and sales activities in this judicial district in collaboration with

defendant Sagent Pharmaceuticals, Inc., including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

9. On information and belief, Defendants caused to be file with the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") for an 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.

Claim for Relief

10. 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.

11. 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®.

12. 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.

13. When it was originally approved by the 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.

14. 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).)

15. 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.

16. 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.

17. 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.

18. 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.

19. On information and belief, Defendants caused to be filed ANDA No. 091684 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.

20. On information and belief, Defendants' 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.

21. On information and belief, Defendants intend to engage in the commercial

manufacture, use, advertising, importation, offer for sale, and/or sales of a generic Acetadote® product promptly upon receiving FDA approval to do so.

22. On information and belief, Defendants have acted in concert, actively aiding, abetting, encouraging, in filing ANDA No. 091684 for "acetylcysteine injection, 200mg/ml" and in preparing to sell, in the United States, a finished dosage pharmaceutical product that will contain acetylcysteine and carry associated labeling pursuant to that ANDA.

The Infringing Conduct by Defendants

Count I - Patent Infringement of the '356 Patent

23. Cumberland realleges and incorporates by reference paragraphs 1-22.

24. 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, Defendants infringed one or more claims of the '356 patent under 35 U.S.C. § 271(e)(2).

25. Defendants have knowledge of the '356 patent, and their actions constitute knowing and willful infringement of the valid '356 patent.

26. As a result of Defendants' 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

27. Cumberland realleges and incorporates by reference paragraphs 1-26.

28. Defendants have 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. Defendants had knowledge of the ’356 patent at least as of May 17, 2012.

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

30. 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, Defendants will knowingly induce medical care providers to infringe the ’356 patent under 35 U.S.C. § 271(b).

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

32. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cumberland on the one hand and Defendants on the other as to liability for the infringement of the ’356 patent. Defendants’ actions constitute a knowing and willful infringement of the ’356 patent. Defendants’ actions have created in Cumberland’s mind a reasonable apprehension of irreparable harm and loss resulting from Defendants’ 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 Defendants’ submission of ANDA No. 091684 constitutes an act of infringement of one or more claims of the ’356 patent under § 271(e)(2);

(C) A declaration that Defendants 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 Defendants’ 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 Defendants 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 Defendants 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 Defendants’ 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: June 26, 2012

/s/ Kristen Healey Cramer
Kristen Healey Cramer (#4512)
Dana K. Severance (#4869)
CONNOLLY BOVE LODGE & HUTZ LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801
Telephone: (302) 888-6317
Facsimile: (302) 658-5614

Laura P. Masurovsky (Of Counsel)
Mark J. Feldstein (Of Counsel)
Danielle A. Duszczyszyn (Of Counsel)
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
Telephone: (202) 408-4000
Facsimile: (202) 408-4400

Attorneys for Plaintiff
CUMBERLAND PHARMACEUTICALS INC.