IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EURAND, INC., CEPHALON, INC., and ANESTA AG, Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc., Anesta AG and Eurand, Inc. (collectively, "Plaintiffs") bring this Complaint against Defendant Impax Laboratories, Inc. ("Impax"), and in support state and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Food and Drug and Patent Laws of the United States, Titles 21 and 35, respectively, arising from Impax filing an Abbreviated New Drug Application with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market generic versions of the drug product AMRIX® (Cyclobenzaprine HCl extended release capsules) prior to the expiration of United States Patent No. 7,387,793 ("the '793 Patent"), which covers the AMRIX® product.

THE PARTIES

2. Plaintiff Eurand, Inc. ("Eurand") is a corporation, organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its office and principal place of business located at 845 Center Drive, Vandalia, Ohio 45377.

3. Plaintiff Cephalon, Inc. ("Cephalon") is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 41 Moores Road, Frazer, Pennsylvania 19355.

4. Plaintiff Anesta AG ("Anesta") is a Swiss corporation having a principal place of business at Baarerstr 23CH-6300 Zug, Switzerland.

5. On information and belief, Defendant Impax is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 30831 Huntwood Avenue, Haywood, CA 94544.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

7. This Court has personal jurisdiction over Impax by virtue, *inter alia*, of its incorporation in Delaware.

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

BACKGROUND

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules the FDA follows when considering whether to approve the marketing of pharmaceutical drugs.

10. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several important aspects. One provision requires innovator drug companies to submit patent information to the FDA "with

respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA then publishes the submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

11. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called the "reference drug") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required to review the patent information that the FDA listed in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to same.

12. The generic drug company may state that it does not seek FDA approval to market its generic drug product prior to patent expiration (a "Paragraph III Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug product prior to patent expiration by stating in its ANDA that the listed patent is "invalid or will not be infringed . . ." (commonly called a "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

13. On July 17, 2008, the United States Patent and Trademark Office ("PTO") duly and legally issued U.S. Patent No. 7,387,793 ("the '793 Patent") to Plaintiff Eurand. A true and correct copy of the '793 Patent is attached hereto as **Exhibit A**.

14. Eurand is the lawful owner by assignment of the '793 Patent and owns all rights, title and interest in the '793 Patent, including all rights needed to bring this patent infringement action.

15. On or about August 23, 2007, Anesta obtained, via an Asset Purchase Agreement ("APA"), all right, title, and interest in approved New Drug Application ("NDA") No. 21-777 for cyclobenzaprine hydrochloride extended-release capsules, in 15mg and 30mg doses, both sold under the AMRIX® trademark. Under the APA, Anesta also obtained an exclusive license to the '793 patent in the United States.

16. Anesta is a wholly-owned subsidiary of Cephalon and was, at all times relevant to this complaint, acting as an agent of Cephalon.

17. The FDA approved AMRIX® for marketing in the United States under NDA No. 21-777, pursuant to section 505(b) of the Federal Food Drug and Cosmetics Act ("FFDCA"), 21 U.S.C. § 355(b).

18. In conjunction with NDA No. 21-777, Anesta listed the '793 Patent in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)).

IMPAX

19. On information and belief, Impax is engaged in the practice of reviewing pharmaceutical patents and challenging those patents.

20. This action arises because of Impax's efforts to gain approval from the FDA to market generic versions of AMRIX® prior to the expiration of the '793 Patent.

21. On information and belief, Impax submitted ANDA No. 90-771 to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). That ANDA seeks FDA approval to commercially manufacture, use, and sell cyclobenzaprine hydrochloride extended-release capsules, 15mg and 30mg ("the Impax Generic Products"), throughout the United States including Delaware. ANDA No. 90-771 specifically seeks FDA approval to market the Impax Generic Products prior to the expiration of the '793 patent.

22. On or about November 25, 2008, Eurand received a letter dated November 24, 2008, and signed by a representative of Impax, purporting to be notice of Impax's filing of an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the '793 Patent. (Impax's "Paragraph IV Notice Letter").

23. On or about November 25, 2008, Cephalon (on behalf of Anesta AG and Anesta Corporation) received the same Impax Paragraph IV Notice Letter dated November 24, 2008, and signed by a representative of Impax, purporting to be notice of Impax's filing of an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the '793 Patent.

24. Impax's Paragraph IV Notice Letters to both Eurand and Cephalon state Impax's intention to seek approval to market generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules prior to the expiration of the '793 Patent.

25. The Impax Paragraph IV Notice Letters sent to both Eurand and Cephalon fail to comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II) because, *inter alia*, they

contain very limited information about the generic formulation for which Impax filed ANDA No. 90-771. For example, the Impax Paragraph IV Notice Letters do not list any of the ingredients in the proposed generic versions, or the amounts of those ingredients. The Impax Paragraph IV Notice Letters also fail to provide any information about the method by which the proposed generic versions are manufactured. In total, the Impax Paragraph IV Notice Letters contain only two sentences about the characteristics of Impax's proposed generic versions of 15mg and 30mg AMRIX® capsules.

26. In the Impax Paragraph IV Notice Letters, Impax offered confidential access to ANDA No. 90-771 on terms and conditions set forth in an attached "Offer of Confidential Access" ("the Impax Offer"). Impax requested that Eurand, Cephalon, and Anesta AG sign the Impax Offer before receiving access to Impax's ANDA No. 90-771. The Impax Offer contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the Impax Offer barred all access by in-house counsel and outside experts. It also unreasonably limited the fields of practice of outside counsel who accepted access to the ANDA.

27. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

28. Since receiving the Impax Paragraph IV Notice Letters and the accompanying Impax Offer, Plaintiffs have attempted to negotiate with Impax to procure a copy of ANDA No. 90-771 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful.

29. Plaintiffs are not aware of any other means of obtaining information regarding the Impax Generic Products within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the Impax Generic Products fall within the scope of one or more claims of the '793 patent.

COUNT I

(Infringement of the '793 Patent Under 35 U.S.C. § 271(e)(2))

30. Paragraphs 1 to 29 are incorporated herein as set forth above.

31. Impax submitted ANDA No. 90-771 to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Impax Generic Products. By submitting the application, Impax committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

32. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry will infringe the '793 patent.

COUNT II
(Declaratory Judgment of Infringement of the '793 Patent Under 35 U.S.C. § 271)

33. Paragraphs 1 to 32 are incorporated herein as set forth above.

34. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

35. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

36. Impax and/or its agents have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import generic versions of AMRIX® products.

37. Impax's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

38. Any commercial manufacture, use, offer for sale, and/or importation of generic versions of AMRIX® by Impax prior to patent expiry will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of the '793 patent.

39. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry will infringe the '793 patent.

EXCEPTIONAL CASE

40. On information and belief, Impax's Paragraph IV certification was baseless, and the arguments presented therein without merit, thereby rendering this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

41. Plaintiffs will be irreparably harmed by Impax's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Impax has infringed the '793 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-771 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute an act of infringement of the '793 patent;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 90-771 shall be a date which is not earlier than the expiration date of the '793 patent including any extensions;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Impax, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with any of them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '793 patent;

d. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271(e)(4)(C) as appropriate;

e. That a declaration be issued under 28 U.S.C. § 2201 that if Impax, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with any of them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '793 patent;

f. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

g. That this Court award such other and further relief as it may deem just and proper.

Dated: January 7, 2009

FISH & RICHARDSON, P.C.

By: _____

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