IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EURAND, INC. and ANESTA AG, Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC. and ANCHEN, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eurand, Inc. and Anesta AG (collectively, "Plaintiffs") bring this Complaint against Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc. (collectively "Anchen" or "Anchen Defendants"), 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 the Anchen Defendants filing an Abbreviated New Drug Application ("ANDA") and an amendment thereto with the United States Food and Drug Administration ("FDA"). The Anchen Defendants' ANDA and amendment to the ANDA seek approval from the FDA to commercially market generic versions of the drug product AMRIX® (Cyclobenzaprine HCl extended release capsules) prior to the expiration of United States Patent Nos. 7,387,793 ("the '793 Patent") and 7,544,372 ("the '372 Patent"), which cover the AMRIX® product and a method of using the AMRIX® product, respectively. Plaintiffs have already filed an action against the Anchen Defendants in this district for infringement of the '793 Patent: Civil Action No. 09-492 (SLR).

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

4. On information and belief, Defendant Anchen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of California, with a principal place of business at 9601 Jeronimo Road, Irvine, CA 92618-2025.

5. On information and belief, Defendant Anchen, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 9601 Jeronimo Road, Irvine, CA 92618-2025.

6. On information and belief, Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc. closely coordinate their commercial activities and hold themselves out to the marketplace as one company. For example, during prosecution of Anchen Pharmaceuticals, Inc.'s trademark application for the word mark ANCHEN with respect to pharmaceutical products (serial no. 77051871), representatives for Anchen Pharmaceuticals, Inc. stated that Anchen Pharmaceuticals, Inc. is a "related entity" to Anchen, Inc. In addition, Anchen Pharmaceuticals, Inc.'s representatives stated that "Anchen Pharmaceuticals, Inc. and Anchen Incorporated, though separate legal entities, constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods." On information and belief, Anchen Pharmaceuticals, Inc. and Anchen, Inc. have also simultaneously shared senior corporate officers with the same titles, including Margaret Choy, Senior Vice President of Regulatory

Affairs. Ms. Choy is also the contact person listed in Anchen's Paragraph IV Notice Letters to Plaintiffs, which are discussed below.

7. On information and belief, Defendant Anchen Pharmaceuticals, Inc. is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States. On information and belief, Defendant Anchen Pharmaceuticals, Inc. conducts its North American operations, in part, through Anchen, Inc. On information and belief, together, they collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) within the United States generally, and the State of Delaware specifically. For example, the Anchen Defendants have sold millions of dollars worth of Bupropion and Divalproex pharmaceutical products within the United States generally, and the State of Delaware specifically, under a stylized "Anchen" trademark (Anchen) that is owned by Anchen, Inc. (serial no. 77037779) (*see* drug labels attached as **Exhibits C and D**).

8. Although the Anchen Defendants' Divalproex product label lists Anchen Pharmaceuticals, Inc. as the source, it identifies the manufacturer as Anchen Pharmaceuticals (Taiwan), Inc. (*See* **Exhibit D**). According to Anchen's website, Anchen Pharmaceuticals (Taiwan), Inc. is a wholly-owned subsidiary of Anchen, Inc. (*see* **Exhibit E** [screen printout of http://www.anchen.com/anchentaiwan.php]).

JURISDICTION AND VENUE

9. 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.

10. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Anchen Defendants.

11. On information and belief, this court has personal jurisdiction over Anchen Pharmaceuticals, Inc. by virtue of its systematic and continuous contacts with the State of Delaware.

12. On information and belief, Anchen Pharmaceuticals, Inc. plans to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, its aforementioned business of preparing generic pharmaceuticals that it distributes in the State of Delaware.

13. This Court has personal jurisdiction over Anchen, Inc. by virtue, *inter alia*, of its incorporation in Delaware.

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

FACTS RELEVANT TO ALL CAUSES

15. On June 17, 2008, the United States Patent and Trademark Office ("PTO") duly and legally issued the '793 Patent to Plaintiff Eurand. A true and correct copy of the '793 Patent is attached hereto as **Exhibit A**.

16. 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.

17. 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.

18. On June 9, 2009, the PTO duly and legally issued the '372 Patent to Plaintiff Eurand. A true and correct copy of the '372 Patent is attached hereto as **Exhibit B**.

19. Eurand is the lawful owner by assignment of the '372 Patent and owns all rights, title and interest in the '372 Patent, including all rights needed to bring this patent infringement action.

20. Under the APA, Anesta has an exclusive license to the '372 Patent in the United States.

21. 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).

22. In conjunction with NDA No. 21-777, Anesta listed both the '793 and '372 Patents in the Orange Book as patents "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)).

23. On or about June 3, 2009 and May 29, 2009, Eurand and Anesta respectively received a letter dated May 28, 2009, and signed by a representative of Anchen, purporting to be notice of Anchen's filing of ANDA No. 91-281 seeking to market 15 mg and 30 mg generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules (the "Anchen Generic Products") 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. (Anchen's "First Paragraph IV Notice Letter").

24. On or about August 13, 2009, Plaintiffs received a letter dated August 13, 2009, and signed by a representative of Anchen, purporting to be notice of Anchen's filing of an amendment to ANDA No. 91-281 seeking to market the Anchen Generic Products in 15 mg and 30 mg dosages and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the '372 Patent. (Anchen's "Second Paragraph IV Notice Letter").

25. Anchen's First Paragraph IV Notice Letter to Plaintiffs stated Anchen's intention to seek approval to market generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules prior to the expiration of the '793 Patent.

26. Anchen's Second Paragraph IV Notice Letter to Plaintiffs states Anchen's intention to seek approval to market generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules prior to the expiration of the '372 Patent.

27. Anchen's First and Second Paragraph IV Notice Letters both 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 Anchen filed ANDA No. 91-281. For example, Anchen's First and Second Paragraph IV Notice Letters do not list any of the ingredients in the proposed generic versions, or the amounts of those ingredients.

28. In Anchen's First and Second Paragraph IV Notice Letters, the Anchen Defendants offered confidential access to portions of ANDA No. 91-281 on terms and conditions set forth in paragraph VII of the Letters ("the Anchen Offers"). The Anchen Defendants requested that Plaintiffs accept the Anchen Offers before receiving access to Anchen's ANDA No. 91-281. The Anchen Offers contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the

Anchen Offers unreasonably limited the fields of practice and other activities of outside counsel and any other person who accepted access to the ANDA.

29. 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."

30. Since receiving Anchen's First and Second Paragraph IV Notice Letters and the accompanying Anchen Offers, Plaintiffs have negotiated with the Anchen Defendants to procure a copy of ANDA No. 91-281 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful. For example, the Anchen Defendants' most recent proposal continues to unreasonably limit the fields of practice and other activities of any person, including outside counsel, who accepts access to the ANDA. The Anchen Defendants have refused to modify these restrictions despite Judge Robinson's June 23, 2009 Order in two other AMRIX® cases pending in this District, CIV-08-889 and CIV-09-018, rejecting similar proposals made by the defendants there. In addition, the Anchen Defendants have refused to provide their ANDA to Plaintiffs under Delaware Local Rule 26.2.

31. Under the Hatch-Waxman Act of 1984, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter ("45-day window") in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

32. Plaintiffs are not aware of any other means of obtaining information regarding the Anchen 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 Anchen Generic Products fall within the scope of one or more claims of the '793 and '372 Patents.

33. On July 7, 2009, within 45 days of receiving Anchen's First Paragraph IV Letter, Plaintiffs filed and served an action against the Anchen Defendants for infringement of the '793 Patent in this District, which is currently pending. *See* Civil Action No. 09-492 (SLR).

COUNT I
(Infringement of the '372 Patent Under 35 U.S.C. § 271(e)(2) against the Anchen Defendants)

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

35. On information and belief, the Anchen Defendants, acting jointly, submitted ANDA No. 91-281 and the amendment thereto 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 Anchen Generic Products. By submitting this application and the amendment thereto, the Anchen Defendants, individually and collectively, committed an act of infringement with respect to the '372 Patent under 35 U.S.C. § 271(e)(2)(A).

36. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Anchen Generic Products prior to patent expiry will infringe the '372 Patent.

COUNT II
(Infringement of the '372 Patent Under 35 U.S.C. § 271 (b) against Anchen, Inc.)

37. Paragraphs 1 to 36 are incorporated herein as set forth above.

38. On information and belief, Anchen, Inc. actively induced Anchen Pharmaceuticals, Inc. to submit ANDA No. 91-281 and the amendment thereto 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 Anchen Generic Products.

39. Upon information and belief, Anchen, Inc. will be actively involved in the manufacture, marketing, and sale of the Anchen Generic Products, should FDA approval be granted.

40. On information and belief, any such commercial manufacture, use, offer for sale, and/or importation of the Anchen Generic Products prior to patent expiry will infringe the '372 Patent. By engaging in a cooperative venture with Anchen Pharmaceuticals, Inc. to submit the ANDA and the amendment thereto to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Anchen Generic Products, Anchen, Inc. committed an act of indirect infringement with respect to the '372 Patent under 35 U.S.C. § 271(b).

COUNT III
(Declaratory Judgment of Infringement of the '372 Patent Under 35 U.S.C. § 271 against the Anchen Defendants)

41. Paragraphs 1 to 40 are incorporated herein as set forth above.

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

43. 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.

44. The Anchen Defendants and/or their 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.

45. The Anchen Defendants' actions indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

46. On information and belief, any commercial manufacture, use, offer for sale, and/or importation of generic versions of AMRIX® by the Anchen Defendants prior to patent expiry will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of the '372 Patent.

47. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Anchen Generic Products, by the Anchen Defendants, prior to patent expiry, will infringe the '372 Patent.

INJUNCTIVE RELIEF

48. Plaintiffs will be irreparably harmed by the Anchen Defendants' 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 the Anchen Defendants, individually and/or collectively, have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-281 and the amendment thereto under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Anchen Generic Products prior to patent expiry will constitute an act of infringement of the '372 Patent;

b. That judgment be entered that Anchen, Inc. has infringed the '372 Patent under 35 U.S.C. § 271(b) by inducing Anchen Pharmaceuticals, Inc. to submit ANDA No. 91-281 and the amendment thereto under the Federal Food Drug, and Cosmetic Act, as a joint

venture in which Anchen, Inc. will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Anchen Generic Products prior to patent expiry, which will constitute an act of infringement of the '372 Patent;

c. 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. 91-281 shall be a date which is not earlier than the expiration date of the '372 Patent including any extensions;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Anchen Pharmaceuticals, Inc., Anchen, Inc., their 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 '372 Patent;

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

f. That a declaration be issued under 28 U.S.C. § 2201 that if Anchen Pharmaceuticals, Inc., Anchen, Inc., their 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 Anchen Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '372 Patent;

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

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

FISH & RICHARDSON P.C.

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