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*Eurand, Inc., Cephalon, Inc., and Anesta AG*

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CENTRAL DISTRICT OF CALIFORNIA  
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IN THE UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA  
SOUTHERN DIVISION

EURAND, INC., CEPHALON, INC.,  
and ANESTA AG,

Plaintiffs,

v.

ANCHEN PHARMACEUTICALS, INC.  
and ANCHEN, INC.,

Defendants.

Civil Action No. CV09-4931 CBM(MLGX)

**COMPLAINT FOR PATENT  
INFRINGEMENT**

Plaintiffs Eurand, Inc., Cephalon, 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:

1 **NATURE OF THE ACTION**

2 1. This is an action for patent infringement under the Food and Drug and  
3 Patent Laws of the United States, Titles 21 and 35, respectively, arising from  
4 Anchen filing an Abbreviated New Drug Application with the United States Food  
5 and Drug Administration (“FDA”), seeking approval to commercially market  
6 generic versions of the drug product AMRIX® (Cyclobenzaprine HCl extended  
7 release capsules) prior to the expiration of United States Patent No. 7,387,793 (“the  
8 ’793 Patent”), which covers the AMRIX® product.

9 **THE PARTIES**

10 2. Plaintiff Eurand, Inc. (“Eurand”) is a corporation, organized, existing  
11 and doing business under and by virtue of the laws of the State of Nevada, with its  
12 office and principal place of business located at 845 Center Drive, Vandalia, Ohio  
13 45377.

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

18 4. Plaintiff Anesta AG (“Anesta”) is a Swiss corporation having a  
19 principal place of business at Baarerstrasse 23CH-6300 Zug, Switzerland.

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

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

26 7. On information and belief, Defendants Anchen Pharmaceuticals, Inc.  
27 and Anchen, Inc. closely coordinate their commercial activities and hold themselves  
28 out to the marketplace as one company. For example, during prosecution of Anchen

1 Pharmaceuticals, Inc.'s trademark application for the word mark ANCHEN with  
2 respect to pharmaceutical products (serial no. 77051871), representatives for  
3 Anchen Pharmaceuticals, Inc. stated that "Anchen Pharmaceuticals, Inc. and  
4 Anchen Incorporated, though separate legal entities, constitute a single source to the  
5 relevant public, and there is unity of control with respect to the nature and quality of  
6 the goods." On information and belief, Anchen Pharmaceuticals, Inc. and Anchen,  
7 Inc. have also simultaneously shared senior corporate officers with the same titles,  
8 including Margaret Choy, Senior Vice President of Regulatory Affairs. Ms. Choy is  
9 also the contact person listed in Anchen's Paragraph IV Notice Letters to Plaintiffs,  
10 which are discussed below.

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

#### 24 **JURISDICTION AND VENUE**

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

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

4 11. On information and belief, this Court has personal jurisdiction over  
5 Anchen, Inc. by virtue of its systematic and continuous contacts with the State of  
6 California.

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

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

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

## 15 **BACKGROUND**

### 16 **Genesis of the Delaware and California Actions**

17 15. As discussed in further detail below, Anchen filed ANDA No. 91-281  
18 seeking to market generic versions of the drug product AMRIX® (Cyclobenzaprine  
19 HCl extended release capsules).

20 16. Cephalon markets and distributes AMRIX® nationwide, including in  
21 California. The filing of ANDA 91-281 evidences an intent by Anchen to compete  
22 with Cephalon and place its product into every market where AMRIX® is currently  
23 found, including California.

24 17. In May 2009, as required by applicable federal law, Anchen sent  
25 Plaintiffs a Paragraph IV letter (defined below) that they had filed ANDA 91-281  
26 with the FDA seeking approval to engage in the commercial manufacture, use or  
27 sale throughout the United States, including California, of a generic version of  
28 Plaintiffs' patented drug product, AMRIX®. 21 U.S.C. § 355(j)(2)(B)(i)(iii).

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

6           19. On July 7, 2009, within the 45-day window, Plaintiffs filed and served  
7 an action against Anchen Pharmaceuticals, Inc. and Anchen, Inc. for infringement of  
8 the patent-in-suit in the United States District Court for the District of Delaware,  
9 Civil Action No. 09-492 (the “Delaware Action”). A copy of the Complaint in the  
10 Delaware Action is attached hereto as Exhibit A.

11           20. Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc. are  
12 properly subject to personal jurisdiction in the District of Delaware and judicial  
13 economy would be promoted by addressing all of Plaintiffs’ claims for  
14 infringement of the patent-in-suit in the Delaware Action. Plaintiffs have filed two  
15 other lawsuits in the District of Delaware against three other generic drug companies  
16 relating to AMRIX® and the patent-in-suit: *Eurand, et al v. Mylan, Inc., et al*, Civ.  
17 No. 08-889 (filed November 26, 2008); and *Eurand, et al v. Impax Labs.*, Civ. No.  
18 09-018 (filed January 7, 2009). The assigned Judge in these lawsuits is the  
19 Honorable Sue Robinson of the District of Delaware.

20           21. Upon information and belief, Plaintiffs understand that Anchen may  
21 nevertheless contest personal jurisdiction in Delaware. The Hatch-Waxman Act  
22 does not address squarely the consequences of the grant of a motion to dismiss for  
23 lack of personal jurisdiction in a plaintiff’s chosen forum. It is possible that such a  
24 dismissal could result in a plaintiff losing the benefit of the 30-month stay of ANDA  
25 approval even if the plaintiff refiled the action in another jurisdiction, since the  
26 refiling would occur after the 45-day window. Therefore, district courts have  
27 countenanced the filing of additional “protective suits” within the 45-day window to  
28 ensure a plaintiff will not lose the benefits of the 30-month stay should the court in

1 the chosen forum dismiss the action for lack of personal jurisdiction. *See e.g.*,  
2 *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 2007 WL 4284877 (W.D.  
3 Mich. Dec. 3, 2007); *PDL Biopharma, Inc. v. Sun Pharmaceutical Industries, Ltd.*,  
4 2007 WL 2261386 (E.D. Mich. Aug. 6, 2007); *Celgene Corp. v. Abrika*  
5 *Pharmaceuticals, Inc.*, 2007 WL 1456156 (D.N.J. May 17, 2007).

6 22. Accordingly, although Plaintiffs believe the District of Delaware has  
7 personal jurisdiction over both Defendants, and Delaware is their preferred choice of  
8 forum to litigate the claims for relief set forth in this Complaint, Plaintiffs beg the  
9 Court's indulgence and file this Complaint as a "protective suit" to protect  
10 Plaintiffs' rights under the Hatch-Waxman Act in the event the District of Delaware  
11 were to determine that there is no personal jurisdiction over the Anchen Defendants  
12 in Delaware.

### 13 FACTS RELEVANT TO ALL CAUSES

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

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

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

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

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

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

8           29. On or about June 3, 2009, Eurand received a letter dated May 28, 2009,  
9 and signed by a representative of Anchen, purporting to be notice of Anchen’s filing  
10 of ANDA No. 91-281 seeking to market 15 mg and 30 mg generic versions of  
11 AMRIX® Cyclobenzaprine HCl extended release capsules (the “Anchen Generic  
12 Products”) and allegedly containing a Paragraph IV Certification required by  
13 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the ’793 Patent. (Anchen’s  
14 “Paragraph IV Notice Letter”).

15           30. On or about May 29, 2009, Cephalon (on behalf of itself and Anesta)  
16 received the same Anchen Paragraph IV Notice Letter dated May 28, 2009, and  
17 signed by a representative of Anchen, purporting to be notice of Anchen’s filing of  
18 an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX®  
19 Cyclobenzaprine HCl extended release capsules and allegedly containing a  
20 Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with  
21 respect to the ’793 Patent.

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

26           32. The Anchen Paragraph IV Notice Letters sent to both Eurand and  
27 Cephalon fail to comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II)  
28 because, *inter alia*, they contain very limited information about the generic

1 formulation for which Anchen filed ANDA No. 91-281. For example, the Anchen  
2 Paragraph IV Notice Letters do not list any of the ingredients in the proposed  
3 generic versions, or the amounts of those ingredients.

4 33. In the Anchen Paragraph IV Notice Letters, Anchen offered  
5 confidential access to portions of ANDA No. 91-281 on terms and conditions set  
6 forth in paragraph VII of the Letters (“the Anchen Offer”). Anchen requested that  
7 Plaintiffs accept the Anchen Offer before receiving access to Anchen’s ANDA No.  
8 91-281. The Anchen Offer contained unreasonable restrictions, above and beyond  
9 those that would apply under a protective order, on who could view the ANDA. For  
10 example, the Anchen Offer unreasonably limited the fields of practice and other  
11 activities of outside counsel and any other person who accepted access to the  
12 ANDA.

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

18 35. Since receiving the Anchen Paragraph IV Notice Letters and the  
19 accompanying Anchen Offer, Plaintiffs have negotiated with Anchen to procure a  
20 copy of ANDA No. 91-281 under restrictions “as would apply had a protective order  
21 been issued.” These negotiations have been unsuccessful. For example, Anchen’s  
22 most recent proposal continues to unreasonably limit the fields of practice and other  
23 activities of any person, including outside counsel, who accepts access to the  
24 ANDA. Anchen has refused to modify these restrictions despite Judge Robinson’s  
25 June 23, 2009 Order in the AMRIX® cases pending in the District of Delaware  
26 rejecting similar proposals made by the defendants there.

27 36. Plaintiffs are not aware of any other means of obtaining information  
28 regarding the Anchen Generic Products within the 45-day statutory period. In the



1 absence of such information, Plaintiffs resort to the judicial process and the aid of  
2 discovery to obtain, under appropriate judicial safeguards, such information as is  
3 required to confirm its allegations of infringement and to present to the Court  
4 evidence that the Anchen Generic Products fall within the scope of one or more  
5 claims of the '793 patent.

6 **COUNT I**

7 **(Infringement of the '793 Patent Under 35 U.S.C. § 271(e)(2)**  
8 **against the Anchen Defendants)**

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

10 38. On information and belief, the Anchen Defendants, acting jointly,  
11 submitted ANDA No. 91-281 to the FDA to obtain approval under the FDCA to  
12 engage in the commercial manufacture, use, or sale throughout the United States,  
13 including California, of the Anchen Generic Products. By submitting this  
14 application, the Anchen Defendants, individually and collectively, committed an act  
15 of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

16 39. On information and belief, any commercial manufacture, use, offer for  
17 sale, sale, and/or importation of the Anchen Generic Products prior to patent expiry  
18 will infringe the '793 patent.

19 **COUNT II**

20 **(Infringement of the '793 Patent Under 35 U.S.C. § 271 (b) against Anchen, Inc.)**

21 40. Paragraphs 1 to 39 are incorporated herein as set forth above.

22 41. On information and belief, Anchen, Inc. actively induced Anchen  
23 Pharmaceuticals, Inc. to submit ANDA No. 91-281 to the FDA to obtain approval  
24 under the FDCA to engage in the commercial manufacture, use, or sale throughout  
25 the United States including California of the Anchen Generic Products. By actively  
26 inducing submission of ANDA No. 91-281, Anchen Inc. has committed an act of  
27 indirect infringement with respect to the '793 patent under 35 U.S.C. § 271(b).

28 42. On information and belief, any commercial manufacture, use, offer for

1 sale, and/or importation of the Anchen Generic Products prior to patent expiry will  
2 infringe the '793 patent.

3 **COUNT III**

4 **(Declaratory Judgment of Infringement of the '793 Patent Under 35 U.S.C.  
5 § 271 against the Anchen Defendants)**

6 43. Paragraphs 1 to 42 are incorporated herein as set forth above.

7 44. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§  
8 2201 and 2202.

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

13 46. The Anchen Defendants and/or their agents have made, and will  
14 continue to make, substantial preparation in the United States to manufacture, sell,  
15 offer to sell, and/or import generic versions of AMRIX® products.

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

18 48. On information and belief, any commercial manufacture, use, offer for  
19 sale, and/or importation of generic versions of AMRIX® by the Anchen Defendants  
20 prior to patent expiry will directly and/or indirectly infringe, contribute to the  
21 infringement of and/or induce infringement of the '793 patent.

22 49. Plaintiffs are entitled to a declaratory judgment that future commercial  
23 manufacture, use, offer for sale, sale, and/or importation of the Anchen Generic  
24 Products, by the Anchen Defendants, prior to patent expiry, will infringe the '793  
25 patent.

26 **INJUNCTIVE RELIEF**

27 50. Plaintiffs will be irreparably harmed by the Anchen Defendants'  
28 infringing activities unless those activities are enjoined by this Court. Plaintiffs do

1 not have an adequate remedy at law.

2 **PRAYER FOR RELIEF**

3 Plaintiffs respectfully pray for the following relief:

4 a. That judgment be entered that the Anchen Defendants,  
5 individually and/or collectively, have infringed the '793 patent under 35 U.S.C. §  
6 271(e)(2)(A) by submitting ANDA No. 91-281 under the Federal Food, Drug, and  
7 Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or  
8 importation of the Anchen Generic Products prior to patent expiry will constitute an  
9 act of infringement of the '793 patent;

10 b. That judgment be entered that Anchen, Inc. has infringed the  
11 '793 patent under 35 U.S.C. § 271(b) by inducing Anchen Pharmaceuticals, Inc. to  
12 submit ANDA No. 91-281 under the Federal Food Drug, and Cosmetic Act, and that  
13 the commercial manufacture, use, offer for sale, sale, and/or importation of the  
14 Anchen Generic Products prior to patent expiry will constitute an act of  
15 infringement of the '793 patent;

16 c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the  
17 effective date of any FDA approval of ANDA No. 91-281 shall be a date which is  
18 not earlier than the expiration date of the '793 patent including any extensions;

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

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

28 f. That a declaration be issued under 28 U.S.C. § 2201 that if

1 Anchen Pharmaceuticals, Inc., Anchen, Inc., their officers, agents, servants,  
2 employees, licensees, representatives, and attorneys, and all other persons acting or  
3 attempting to act in active concert or participation with any of them or acting on  
4 their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or  
5 importation of the Anchen Generic Products prior to patent expiry, it will constitute  
6 an act of direct and/or indirect infringement of the '793 patent;

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

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

11 Dated: July 9, 2009

FISH & RICHARDSON P.C.

12 By:   
13 \_\_\_\_\_

Jonathan E. Singer (SBN 187908)

14 Attorneys for Plaintiffs

15 *Eurand, Inc., Cephalon, Inc., and Anesta AG*

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