IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

EURAND, INC., CEPHALON, INC., and ANESTA AG, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., and MYLAN INC., Defendants.	CASE NO. **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Eurand, Inc., Cephalon, Inc. and Anesta AG (collectively, "Plaintiffs") bring this Complaint against Defendants Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively "Mylan" or "Mylan 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 Mylan Defendants filing an Abbreviated New Drug Application with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market a generic version 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 Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.

7. On information and belief, Defendant Mylan Inc. is the parent company of Mylan Pharmaceuticals, and Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

8. On information and belief, Defendant Mylan Pharmaceuticals is in the business of preparing generic pharmaceuticals that it distributes in the State of West Virginia and throughout the United States. On information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Mylan Pharmaceuticals. 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 West Virginia specifically.

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 Defendant Mylan Inc..

11. This Court has personal jurisdiction over Mylan Pharmaceuticals by virtue, *inter alia*, of its incorporation in West Virginia.

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

BACKGROUND

13. 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.

14. 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").

15. 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. § 255(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.

16. 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).

17. 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**.

18. 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.

19. 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.

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

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 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).

MYLAN

23. On information and belief, the Mylan Defendants are engaged in the practice of reviewing pharmaceutical patents and challenging those patents.

24. This action arises because of the Mylan Defendants' efforts to gain approval from the FDA to market a generic version of AMRIX® prior to the expiration of the '793 Patent.

25. On information and belief, Defendant Mylan Pharmaceuticals, jointly with, and/or as the agent or alter ego of its parent Mylan Inc., submitted ANDA No. 90-738 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 Mylan Generic Products"), throughout the United States including West Virginia. ANDA No. 90-738 specifically seeks FDA approval to market the Mylan Generic Products prior to the expiration of the '793 patent.

26. On or about October 21, 2008, Eurand received a letter dated October 16, 2008, and signed by an attorney on behalf of Mylan, purporting to be notice of Mylan's filing of an ANDA seeking to market a 15 mg and 30 mg generic version 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. (Mylan's "Paragraph IV Notice Letter").

27. On or about October 17, 2008, Cephalon (on behalf of Anesta Corp.) received the same Mylan Paragraph IV Notice Letter dated October 16, 2008, and signed by an attorney on behalf of Mylan, purporting to be notice of Mylan's filing of an ANDA seeking to market a 15 mg and 30 mg generic version 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.

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

29. The Mylan 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 Mylan filed ANDA No. 90-738. For example, the Mylan Paragraph IV Notice Letters do not list any of the

ingredients in the proposed generic version, or the amounts of those ingredients. The Mylan Paragraph IV Notice Letters also fail to provide any information about the method by which the proposed generic version is manufactured. In total, the Mylan Paragraph IV Notice Letters contain only a single sentence about the characteristics of Mylan's proposed generic versions of 15mg and 30mg AMRIX® capsules. Moreover, the Mylan Paragraph IV Notice Letters were not sent by registered or certified mail, return receipt requested, as required under 21 C.F.R. § 314.95(a). Instead, the Mylan Paragraph IV Notice Letters were sent by Federal Express.

30. In the Mylan Paragraph IV Notice Letters, Mylan offered confidential access to portions of ANDA No. 90-738 on terms and conditions set forth in an attached "Offer of Confidential Access" ("the Mylan Offer"). Mylan requested that Eurand, Cephalon, and Anesta Corp. sign the Mylan Offer before providing access to any portion of Mylan's ANDA No. 90-738. The Mylan Offer contained various restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the Mylan Offer barred any access to in-house counsel and outside experts, and substantially limited the fields of practice of outside counsel who might view the ANDA.

31. 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."

32. Since receiving the Mylan Paragraph IV Notice Letters and the accompanying Mylan Offer, Plaintiffs have attempted to negotiate with Mylan to procure a copy of ANDA No. 90-738 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful. For example, Mylan's most recent proposal unduly limits

outside and in-house attorney access, and offers only those portions of the ANDA that Mylan deems "relevant."

33. Plaintiffs are not aware of any other means of obtaining information regarding the Mylan 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 Mylan 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) against Mylan)

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

35. The Mylan Defendants, acting jointly, submitted ANDA No. 90-738 to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States, including West Virginia, of the Mylan Generic Products. By submitting the application, the Mylan Defendants, individually and collectively, committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

36. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 90-738 to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States, including West Virginia, of the Mylan Generic Products. By submitting the application, Mylan Pharmaceuticals has committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

37. When Mylan Pharmaceuticals submitted ANDA No. 90-738 to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of the Mylan Generic Products throughout the United States, including West Virginia, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit the application and/or causing its agent or alter ego to submit the application, Mylan Inc. committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

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

COUNT II
(Infringement of the '793 Patent Under 35 U.S.C. § 271(b) against Mylan Inc.)

39. Paragraphs 1 to 38 are incorporated herein as set forth above.

40. Mylan Inc. actively induced Mylan Pharmaceuticals to submit ANDA No. 90-738 to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States including West Virginia of the Mylan Generic Products. By actively inducing submission of ANDA No. 90-738, Mylan Inc. has committed an act of indirect infringement with respect to the '793 patent under 35 U.S.C. § 271(b).

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

COUNT III
(Declaratory Judgment of Infringement of the '793 Patent Under 35 U.S.C. § 271(a) against Mylan)

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

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

44. 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.

45. Each of the Mylan Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import their generic versions of AMRIX® products.

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

47. Any commercial manufacture, use, offer for sale, and/or importation of generic versions of AMRIX® prior to patent expiry will infringe the '793 patent.

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

EXCEPTIONAL CASE

49. Mylan Pharmaceuticals was aware of the '793 patent prior to filing ANDA No. 90-738.

50. Mylan Inc. was aware of the '793 patent prior to filing ANDA No. 90-738.

51. The willful and deliberate infringing actions of Mylan Inc. and Mylan Pharmaceuticals, individually and collectively, render this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

52. Plaintiffs will be irreparably harmed by 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:

JUDGMENT AGAINST MYLAN

a. That judgment be entered that the Mylan Defendants, individually and/or collectively, have infringed the '793 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-738 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Mylan Generic Products prior to patent expiry will constitute an act of infringement of the '793 patent;

b. That judgment be entered that Mylan Inc. has infringed the '793 patent under 35 U.S.C. § 271(b) by inducing Mylan Pharmaceuticals to submit ANDA No. 90-738 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Products prior to patent expiry will constitute an act of infringement of the '793 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. 90-738 shall be a date which is not earlier than the expiration date of the '793 patent including any extensions;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan Inc., Mylan Pharmaceuticals, 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 '793 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 Mylan Inc., Mylan Pharmaceuticals, 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 Mylan Generic Products prior to patent expiry, it will constitute an act of infringement of the '793 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.

Respectfully submitted,

Dated: November 26, 2008

By: _____

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