IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EURAND, INC. and ANESTA AG,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD. and BARR LABORATORIES, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eurand, Inc. and Anesta AG (collectively, "Plaintiffs") bring this Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and Barr Laboratories, Inc. ("Barr") (collectively, "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 Barr and Teva USA's filing of an Abbreviated New Drug Application ("ANDA") and a supplement thereto with the United States Food and Drug Administration ("FDA"). Barr and Teva USA's ANDA and supplement 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 methods of using the AMRIX® product,

respectively. Plaintiffs have already filed an action against Barr in this district for infringement of the '793 Patent: Civil Action No. 08-889 (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 Teva USA is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19002.

5. On information and belief, Defendant Teva USA is a wholly-owned subsidiary of Teva Ltd.

6. On information and belief, Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, with a principal place of business at 5 Basel Street, St. Petach Tikva 49131, Israel.

7. On information and belief, Defendant Barr is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677.

8. On information and belief, Defendant Barr is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc.

9. On information and belief, Barr Pharmaceuticals, Inc. is a wholly-owned subsidiary of Teva Ltd.

10. On information and belief, Defendant Barr 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 Teva USA conducts its North American operations, in part, through Barr. On information and belief, Defendant Teva Ltd. directs the actions of and acts in concert with Defendants Barr and Teva USA. On information and belief, the Defendants, together, collaborate in the manufacturing, 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.

JURISDICTION AND VENUE

11. 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.

12. This Court has personal jurisdiction over Barr because, *inter alia*, it is incorporated in Delaware.

13. This Court has personal jurisdiction over Teva USA because, *inter alia*, it is incorporated in Delaware.

14. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, on information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries, including Defendants Barr and Teva USA, conducts business within the judicial district. On information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries, including Defendants Barr and Teva USA, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Moreover, Teva Ltd. has previously submitted to the jurisdiction of this Court

and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

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

FACTS RELEVANT TO ALL CAUSES

16. 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**.

17. 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.

18. 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.

19. 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**.

20. 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.

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

22. 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).

23. 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).

24. On or about October 29, 2008, Plaintiffs received a letter dated October 28, 2008, and signed by a representative of Barr, purporting to be notice of Barr's filing of ANDA No. 90-864 seeking to market 15 mg and 30 mg generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules (the "Defendants' 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 (the "First Paragraph IV Notice Letter").

25. On or about September 21, 2009, Plaintiff Eurand received a letter dated September 18, 2009, and signed by a representative of Defendants Barr and Teva USA, purporting to be notice of Barr and Teva USA's filing of a supplement to ANDA No. 90-864 seeking to market the Defendants' 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 (the "Second Paragraph IV Notice Letter").

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

27. The Second Paragraph IV Notice Letter to Plaintiff Eurand states Barr and Teva USA's intention to seek approval to market generic versions of AMRIX® Cyclobenzaprine HCl extended release capsules prior to the expiration of the '372 Patent.

28. 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 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).

29. On November 25, 2008, within 45 days of receiving the First Paragraph IV Letter, Plaintiffs filed and served an action against Barr for infringement of the '793 Patent in this District, which is currently pending. *See* Civil Action No. 08-889 (SLR).

COUNT I
(Infringement of the '372 Patent Under 35 U.S.C. § 271(e)(2) against Barr and Teva USA)

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

31. On information and belief, Defendants, acting jointly, submitted ANDA No. 90-864 and the supplement 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 Defendants' Generic Products. By submitting this application and the supplement thereto, Defendants Barr and Teva USA, individually and collectively, committed an act of infringement with respect to the '372 Patent under 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' 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 Teva USA and Teva Ltd.)

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

34. On information and belief, knowing of the '372 Patent, and knowing that the act of submitting an ANDA to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale in the United States of the Defendants' Generic Products prior to patent expiry would be an act of patent infringement under 35 U.S.C. § 271(e)(2)(A), Teva USA knowingly induced Barr to submit ANDA No. 90-864 and the supplement 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 Defendants' Generic Products.

35. On information and belief, knowing of the '372 Patent, and knowing that the act of submitting an ANDA to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale in the United States of the Defendants' Generic Products prior to patent expiry would be an act of patent infringement under 35 U.S.C. § 271(e)(2)(A), Teva Ltd. knowingly inducing Defendants Barr and Teva USA to submit ANDA No. 90-864 and the supplement 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 Defendants' Generic Products.

36. On information and belief, Teva USA and Teva Ltd. will be actively involved in the manufacture, marketing, and sale of the Defendants' Generic Products, should FDA approval be granted.

37. On information and belief, any such commercial manufacture, use, offer for sale, and/or importation of the Defendants' Generic Products prior to patent expiry will infringe the

'372 Patent. By engaging in a cooperative venture with Barr to submit the ANDA and the supplement 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 Defendants' Generic Products, Teva USA committed an act of indirect infringement with respect to the '372 Patent under 35 U.S.C. § 271(b). By engaging in a cooperative venture with Barr and Teva USA to submit the ANDA and the supplement 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 Defendants' Generic Products, Teva Ltd. 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 all Defendants)

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

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

40. 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.

41. 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.

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

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

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

INJUNCTIVE RELIEF

45. 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:

a. That judgment be entered that Defendants Teva USA and Barr, individually and/or collectively, have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-864 and the supplement thereto under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Defendants' Generic Products prior to patent expiry will constitute an act of infringement of the '372 Patent;

b. That judgment be entered that Teva USA has infringed the '372 Patent under 35 U.S.C. § 271(b) by knowingly inducing Barr to submit ANDA No. 90-864 and the supplement thereto under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Teva USA will participate in the commercial manufacture, use, offer for sale, sale, and/or

importation of the Defendants' Generic Products prior to patent expiry, which will constitute an act of infringement of the '372 Patent;

c. That judgment be entered that Teva Ltd. has infringed the '372 Patent under 35 U.S.C. § 271(b) by knowingly inducing Barr and Teva USA to submit ANDA No. 90-864 and the supplement thereto under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Teva Ltd. will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' Generic Products prior to patent expiry, which will constitute an act of infringement of the '372 Patent;

d. 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. 90-864 shall be a date which is not earlier than the expiration date of the '372 Patent including any extensions;

e. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Teva USA, Teva Ltd., Barr, 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;

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

g. That a declaration be issued under 28 U.S.C. § 2201 that if Teva USA, Teva Ltd., Barr, 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 Defendants' Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '372 Patent;

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

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

FISH & RICHARDSON P.C.

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