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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Eagle Pharmaceuticals, Inc., Plaintiff, v. Sandoz Inc., Defendant.	Case No. _____ CIVIL ACTION **COMPLAINT**

STATEMENT PURSUANT TO L. CIV. R. 10.1

Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware and has a principal place of business at 470 Chestnut Ridge Road in Woodcliff Lake, New Jersey 07677. For its Complaint against Defendant Sandoz Inc., Plaintiff alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 7,589,106 (the "'106 patent") and 7,687,516 (the "'516 patent") pursuant to the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

PARTIES

2. Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business in Woodcliff Lake, New Jersey.

3. Upon information and belief, Defendant Sandoz Inc. is a corporation organized under the laws of the State of Colorado, with its principal place of business in Princeton, New

Jersey.

JURISDICTION

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271(e)(2).

5. This Court has personal jurisdiction over Defendant by virtue of the fact that Defendant's principal place of business is within this judicial district.

VENUE

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PATENTS-IN-SUIT

7. Plaintiff is the lawful owner of the '106 patent and the '516 patent, including all rights to sue and recover for infringement.

8. The '106 patent, entitled "Alcohol Free Formulation of Argatroban," duly and legally issued on September 15, 2009, naming Nageswara R. Palepu as inventor. A copy of the '106 patent is attached as Exhibit A.

9. The '516 patent, entitled "Alcohol Free Formulation of Argatroban," duly and legally issued on March 30, 2010, naming Nageswara R. Palepu as inventor. A copy of the '516 patent is attached as Exhibit B.

ARGATROBAN IN SODIUM CHLORIDE

10. Plaintiff is the holder of New Drug Application ("NDA") No. 022434 for Argatroban in Sodium Chloride (argatroban) injectable, intravenous infusion, 50 mg/ 50 mL.

11. On June 29, 2011, the U.S. Food and Drug Administration ("FDA") approved NDA No. 022434 for the manufacture, marketing, and sale of Argatroban in Sodium Chloride injectable, intravenous infusion for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia and also as an anticoagulant in adult patients with or at risk of heparin-induced thrombocytopenia undergoing percutaneous coronary intervention. Plaintiff sells Argatroban in Sodium Chloride under NDA No. 022434.

12. The '106 and '516 patents are listed in the FDA's *Approved Drug Products with*

Therapeutic Equivalence Evaluations (the "Orange Book") for Argatroban in Sodium Chloride.

DEFENDANT'S ANDA

13. Upon information and belief, Defendant submitted Abbreviated New Drug Application ("ANDA") No. 203743 to the FDA under 35 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of argatroban injectable, intravenous infusion (50 mg/ 50 mL) ("Defendant's Generic Product") before expiration of the '106 and '516 patents.

14. Upon information and belief, ANDA No. 203743 refers to and relies upon Plaintiff's NDA for Argatroban in Sodium Chloride to demonstrate safety and efficacy for Defendant's Generic Product.

15. Plaintiff received from Defendant a letter dated February 16, 2012 (the "Notification Letter"), stating that ANDA No. 203743 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '106 and '516 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Defendant's Generic Product.

16. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), an ANDA applicant must provide with its notification letter "a detailed statement of the factual and legal bases of the opinion of the applicant that the patent is invalid or will not be infringed." If the applicant contends that the patent will not be infringed by its proposed generic product, its notice must include "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed." 21 C.F.R. § 314.95(c)(6)(i).

17. Defendant included with its Notification Letter a document entitled "Sandoz, Inc.'s Detailed Statement of the Factual and Legal Bases for its Opinion that U.S. Patent Nos. 7,589,106 and 7,687,516 are Invalid, Unenforceable and/or Not Infringed by the Manufacture, Use, Importation, Sale or Offer for Sale of the Sandoz Product" ("Detailed Statement"). The Detailed Statement did not include any factual or legal basis of any opinion by Defendant that Defendant's Generic Product does not infringe the claims of the '106 and '516 patents.

18. Accordingly, the Notification Letter evidences Defendant's lack of opinion or

belief that Defendant's Generic Product does not infringe the claims of the '106 and '516 patents.

19. Plaintiff commenced this action within 45 days of receiving the Notification Letter.

COUNT ONE

(Infringement of the '106 Patent under 35 U.S.C. § 271(e)(2))

20. Plaintiff reasserts and realleges paragraphs 1-19 above as if fully set forth herein.

21. Defendant's submission of ANDA No. 203743 to the FDA with a Paragraph IV certification regarding the '106 patent, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant's Generic Product before the expiration of the '106 patent, constitutes infringement of the '106 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT TWO

(Declaratory Judgment of Infringement of the '106 Patent under 35 U.S.C. § 271(a)-(c))

22. Plaintiff reasserts and realleges paragraphs 1-21 above as if fully set forth herein.

23. Upon information and belief, Defendant intends, soon after the FDA has approved its ANDA No. 203743, to begin manufacturing, marketing, offering to sell, or selling within the United States Defendant's Generic Product.

24. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, or sell within the United Sates, and/or import into the United States of Defendant's Generic Product before expiration of the '106 patent.

25. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United Sates, and/or importation into the United States of Defendant's Generic Product before expiration of the '106 patent.

26. Defendant's actions, including without limitation the filing of ANDA No. 203743, exhibit a refusal to change the course of its action despite Plaintiff's patent rights.

27. Upon information and belief, commercial manufacture, use, offer for sale, or sale

within the United States, and/or importation into the United States of Defendant's Generic Product before expiration of the '106 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '106 patent.

28. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendant's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendant's Generic Product before expiration of the '106 patent by Defendant or its agents, will infringe the '106 patent.

COUNT THREE

Infringement of the '516 Patent under 35 U.S.C. § 271(e)(2))

29. Plaintiff reasserts and realleges paragraphs 1-28 above as if fully set forth herein.

30. Defendant's submission of ANDA No. 203743 to the FDA with a Paragraph IV certification regarding the '516 patent, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant's Generic Product before the expiration of the '516 patent, constitutes infringement of the '516 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT FOUR

(Declaratory Judgment of Infringement of the '516 Patent under 35 U.S.C. § 271(a)-(c))

31. Plaintiff reasserts and realleges paragraphs 1-30 above as if fully set forth herein.

32. Upon information and belief, Defendant intends, soon after the FDA has approved its ANDA No. 203743, to begin manufacturing, marketing, offering to sell, or selling within the United States Defendant's Generic Product.

33. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, or sell within the United Sates, and/or import into the United States of Defendant's Generic Product before expiration of the '516 patent.

34. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture,

use, offer for sale, or sale within the United Sates, and/or importation into the United States of Defendant's Generic Product before expiration of the '516 patent.

35. Defendant's actions, including without limitation the filing of ANDA No. 203743, exhibit a refusal to change the course of its action despite Plaintiff's patent rights.

36. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendant's Generic Product before expiration of the '516 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '516 patent.

37. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendant's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendant's Generic Product before expiration of the '516 patent by Defendant or its agents, will infringe the '516 patent.

INJUNCTIVE RELIEF

38. Plaintiff will be substantially and irreparably damaged and harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Enter a judgment that Defendant has infringed the '106 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203743 to the FDA, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant's Generic Product before expiration of the '106 patent;

B. Enter a declaration under 28 U.S.C. § 2201 that Defendant would infringe the '106 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Defendant's Generic Product before expiration of

the ’106 patent;

C. Enter a judgment that Defendant has infringed the ’516 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203743 to the FDA, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant’s Generic Product before expiration of the ’516 patent;

D. Enter a declaration under 28 U.S.C. § 2201 that Defendant would infringe the ’516 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Defendant’s Generic Product before expiration of the ’516 patent;

E. Enter an order under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 203743, if any, shall be no earlier than the date of expiration of each patent-in-suit Defendant is found to infringe, including any extensions;

F. Enter an injunction under 35 U.S.C. §§ 271(e)(4)(B) and 283 permanently enjoining Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offers to sell, or sale within the United States, or importation into the United States, of Defendant’s Generic Product before the expiration of each patent-in-suit Defendant is found to infringe, including any extensions;

G. Grant Plaintiff compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendant commercially manufactures, uses, offers for sale, or sells in the United States, or imports into the United States, Defendant’s Generic Product before the expiration of any patent-in-suit Defendant is found to infringe, including any extensions;

H. Declare that Defendant’s activities have made this an exceptional case under 35

U.S.C. §285 and grant Plaintiff its attorneys' fees; and

I. Award Plaintiff any further and additional relief as this Court may deem just and proper.

Respectfully submitted,

LATHAM & WATKINS LLP

Dated: March 29, 2012

By s/ Alan E. Kraus
Alan E. Kraus

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*Shall seek *pro hac vice* admission