IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANDOZ INC.
506 Carnegie Center, Suite 400
Princeton, NJ 08540,

Plaintiff,

v.

BOEHRINGER INGELHEIM
International GmbH
Binger Strasse 173
Ingelheim, Germany 55216.

Defendant.

Case: 1:10-cv-01767
Assigned To : Kennedy, Henry H.
Assign. Date : 10/19/2010
Description: General Civil

COMPLAINT FOR DECLARATORY RELIEF

Plaintiff Sandoz Inc. ("Sandoz") by its undersigned attorneys, alleges as follows:

PARTIES

1. Plaintiff Sandoz is a corporation existing under the laws of the State of Colorado, with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540. Sandoz is a leader in the manufacture and marketing of generic drugs.

2. Upon information and belief, defendant Boehringer Ingelheim International GmbH ("Boehringer") is a corporation existing under the laws of Germany with its principal place of business at Binger Strasse 173, Ingelheim, Germany 55216.

3. Boehringer is one of a number of Boehringer Ingelheim companies, including Boehringer Ingelheim Pharma GmbH & Co. KG, involved in, among other things, the development, production, and marketing of branded and generic prescription medicines.

JURISDICTION

4. This is an action for declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining a question of actual controversy between the parties regarding the validity and infringement of a United States patent, as herein more fully appears.

5. This court has jurisdiction over the action pursuant to 21 U.S.C. § 355(j)(5)(C)(i), 35 U.S.C. § 271(e)(5) (civil action to obtain patent certainty), 28 U.S.C. §§ 1331 (federal question), and 1338(a) (action relating to patents).

6. This court has personal jurisdiction over Boehringer pursuant to 35 U.S.C. § 293 (personal jurisdiction over nonresident patentees).

VENUE

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c) and (d).

FACTUAL BACKGROUND

8. United States Patent No. 7,429,602 (the "'602 patent"), entitled "Treating Conjunctivitis by Topically Administering An Epinastine Solution to the Conjunctiva" issued to inventors V. Trach and G. Duschler on September 30, 2008. A true and correct copy of the '602 patent is attached hereto as Exhibit A.

9. Boehringer Ingelheim Pharma GmbH & Co. KG is named as the assignee on the face of the '602 patent.

10. Pursuant to an assignment recorded on September 7, 2007 (Reel 019796/Frame 0095), Boehringer Ingelheim Pharma GmbH & Co. KG assigned its entire interest in the '602 patent to defendant Boehringer. A true and correct copy of this assignment document is attached hereto as Exhibit B.

11. Upon information and belief, defendant Boehringer is the owner of all rights in the '602 patent.

12. Allergan, Inc. ("Allergan") is a licensee of the '602 patent and holds approved New Drug Application ("NDA") number 21-565 permitting it to market and sell 0.05% Epinastine Hydrochloride Ophthalmic Solutions. Allergan currently markets this medication as ELESTAT®.

13. Boehringer caused the '602 patent to be listed in the Food and Drug Administration's ("FDA's") *Approved Drug Products with Therapeutic Equivalence Evaluation* listing (the "Orange Book") for 0.05% Epinastine Ophthalmic Solutions.

14. By listing, or causing to be listed, the '602 patent in the Orange Book Boehringer asserted that making or using 0.05% Epinastine Ophthalmic Solutions infringes one or more claims of the '602 patent.

15. Sandoz submitted Abbreviated New Drug Application ("ANDA") number 90-950 to the FDA on October 15, 2008 seeking approval to manufacture and sell Epinastine Hydrochloride Ophthalmic Solution 0.05% (the "Sandoz ANDA Product"), a generic version of ELESTAT®.

16. On October 17, 2008 Sandoz amended the 90-950 ANDA to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), stating that the '602 patent was invalid or would not be infringed by Sandoz's ANDA Product. Sandoz was not the first entity to file such a certification.

17. Sandoz does not know what entity was the first to file a Paragraph IV certification for 0.05% Epinastine Hydrochloride Ophthalmic Solutions.

18. By letter dated January 16, 2009 Sandoz gave notice, pursuant to 21 U.S.C. § 355(j)(2)(B), of the 90-950 ANDA and its Paragraph IV certification to, among others, the NDA holder Allergan, Boehringer Ingelheim Pharma GmbH & Co. KG, the assignee listed on

the face of the '602 patent, and other Boehringer Ingelheim entities. This notice letter included a detailed explanation of the basis for Sandoz's assertion that the '602 patent was invalid or not infringed by Sandoz's ANDA Product.

19. Sandoz received no response to this notice letter.

20. On July 31, 2009 Sandoz filed a declaratory judgment action in the United States District Court for the District of Columbia seeking a judicial declaration that the '602 patent is invalid, unenforceable, or would not be infringed by Sandoz's ANDA Product. This action was given Case No. 09-cv-01444-JR.

21. On August 25, 2009 defendant Boehringer filed a statutory disclaimer pursuant to 35 U.S.C. § 253 with the United States Patent and Trademark Office (the "Disclaimer") disclaiming all of the claims and the entire term of the '602 patent. A true and correct copy of this disclaimer is attached hereto as Exhibit C.

22. Boehringer subsequently submitted a request to the FDA asking that the '602 patent be removed from the Orange Book listing for 0.05% Epinastine Ophthalmic Solutions.

23. On October 5, 2010 Sandoz dismissed Case No 09-cv-01444-JR without prejudice.

24. The entry for 0.05% Epinastine Ophthalmic Solutions in the Orange Book listing on the FDA's web site indicates that the delisting request has been received, but the '602 patent continues to appear in that listing.

25. Sandoz intends to market its 0.05% Epinastine Ophthalmic Solutions in the United States as soon as legally permissible after approval of the 90-950 ANDA.

26. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I), the FDA cannot approve an ANDA application by an applicant who was not first to make a Paragraph IV certification until 180-days

after the date of the first commercial marketing by the first applicant to make a Paragraph IV certification. This term is commonly referred to as the "180-day exclusivity period."

27. Pursuant to 21 U.S.C. § 355(j)(5)(D), a first applicant can forfeit the 180-day exclusivity period under a number of circumstances, including failing to market their drug in a timely fashion after a final judicial determination of invalidity or noninfringement of the patent subject to the Paragraph IV certification.

28. Since Sandoz was not the first to make a Paragraph IV certification for the '602 patent, the FDA will not approve Sandoz's ANDA until the 180-day exclusivity period for the '602 patent has expired or been forfeited pursuant to 21 U.S.C. § 355(j)(5)(D).

29. No applicant has marketed a generic 0.05% Epinastine Ophthalmic Solution, and the 180-day exclusivity period for the '602 patent has not expired.

30. Based on Sandoz's intent to launch its generic 0.05% Epinastine Ophthalmic Solutions as soon as legally permissible, and the fact that the FDA will not approve Sandoz's ANDA until the 180-day exclusivity period has run or been forfeited, an actual and justiciable controversy exists between Boehringer and Sandoz regarding validity and infringement of the '602 patent. *See Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, Case No. 2009-1593, __ F.3d __ (Fed. Cir. October 6, 2010).

FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity and Unenforceability of the '602 patent)

31. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1-30 of this Complaint.

32. In the August 25, 2009 Disclaimer Boehringer disclaimed "all claims in and the entire term of" the '602 patent.

33. By the express terms of the Disclaimer, and by operation of 35 U.S.C. § 253, no claim of the '602 patent remains valid or enforceable.

34. This judicial declaration is necessary and appropriate in order that Sandoz may ascertain its rights and duties with respect to the '602 patent.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment of Noninfringement of the '602 patent)

35. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1-34 of this Complaint.

36. The Sandoz 0.05% Epinastine Hydrochloride Ophthalmic Solution product described in the 90-950 ANDA does not infringe any claim of the '602 patent.

37. This judicial declaration is necessary and appropriate in order that Sandoz may ascertain its rights and duties with respect to the '602 patent.

PRAYER FOR RELIEF

Wherefore, Sandoz Inc. prays for a judgment against defendant Boehringer Ingelheim International GmbH as follows:

(a) That the Court declare that each and every claim of the '602 patent is invalid and unenforceable;

(b) That the Court declare that the 0.05% Epinastine Hydrochloride Ophthalmic Solution described in Sandoz's 90-950 ANDA does not infringe any claim of the '602 patent;

(c) That the Court deem this case "exceptional" within the meaning of 35 U.S.C. § 285 entitling Sandoz to an award of its reasonable attorneys fees and expenses in this action; and

(d) That the Court grant such other and further relief as the Court may deem just and proper.

Dated: October 19, 2010

Respectfully submitted,

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