IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd. and Allergan, Inc. Plaintiffs, v. Apotex Inc. and Apotex Corp. Defendants.	)	C.A. No.: 12-159 (SLR)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd., ("Senju"), Kyorin Pharmaceutical Co., Ltd. ("Kyorin") and Allergan, Inc. ("Allergan") (collectively "Plaintiffs") allege for their complaint against Apotex Inc. and Apotex Corp. (collectively "Defendants" or "Apotex") as follows:

Nature of the Action

1. This is an action for infringement of United States Patent No. 6,333,045 ("the '045 Patent"), specifically, Claims 12, and 14-16 set forth on the '045 Patent reexamination certificate, under 35 U.S.C. §271(e)(2) and also seeks a declaratory judgment that reexamined claim 6 of the '045 patent is infringed.

The Parties

2. Plaintiff Senju is a corporation organized under the laws of Japan having a place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

3. Plaintiff Kyorin is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311 Japan.

4. Plaintiff Allergan is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

5. On information and belief, defendant Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

6. On information and belief, defendant Apotex Corp. offers for sale and sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

7. On information and belief, defendant Apotex, Inc. is a corporation organized under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

8. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

9. On information and belief, Apotex, Inc. is formulating and/or plans to formulate gatifloxacin ophthalmic solution to be marketed and sold in the United States by Apotex Corp. Plaintiffs reserve the right to amend the complaint to substitute a different party for Apotex Inc. and/or Apotex Corp. if, through discovery, Plaintiffs discover that a company other than Apotex, Inc. and/or Apotex Corp. is formulating and/or marketing and/or selling gatifloxacin ophthalmic solution.

10. On information and belief, the acts of Apotex Corp. complained of herein were done with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of Apotex, Inc.

Jurisdiction and Venue

11. This action arises under 35 U.S.C. Section 1, *et seq.* This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Apotex because of its continuous and systematic contacts with Delaware. On information and belief, Apotex directly or indirectly purposefully sells, markets, distributes, and manufactures, goods for sale in the United States and Delaware; derives substantial revenue from things used or consumed in Delaware, regularly does and solicits business in Delaware; has filed counterclaims in this Court in other actions purposefully availing itself of the rights and benefits of this Court; and has admitted and/or consented to jurisdiction in this Court on numerous occasions, including with respect to another litigation involving gatifloxacin ophthalmic solutions versus the same Plaintiffs, *e.g., Senju Pharmaceuticals Co., Ltd et al.* v. *Apotex Inc. et al.*, 07-779 (D. Del.).

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

Background

14. The ‘045 Patent, entitled “Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin,” issued on December 25, 2001. A copy of the ‘045 Patent, reexamination certificate, and certificate of correction is attached to this complaint as Exhibit A.

15. Senju and Kyorin jointly own the entire right and interest in the ‘045 Patent.

16. Allergan is the exclusive licensee of the ‘045 Patent for ophthalmic uses.

17. Each claim of the reexamined ‘045 Patent has a statutory presumption of validity that exists at all stages of a proceeding.

18. The ’045 Patent was previously asserted by Plaintiffs against Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al*., 07-779 (D.

Del.).

19. On June 21, 2010, the United States District Court for the District of Delaware entered judgment that Claims 1-3 and 6-9 of the '045 Patent were invalid as obvious.

20. On November 3, 2010, the United States District Court for the District of Delaware reopened the record to take additional testimony with respect to claim 7 of the '045 Patent.

21. On December 20, 2011, the United States District Court for the District of Delaware entered judgment that Claim 7 of the '045 patent was invalid as obvious.

22. Plaintiffs are appealing the district court's judgment with respect to Claim 7 of the '045 Patent from the United States District Court for the District of Delaware to the United States Court of Appeals for the Federal Circuit.

23. On February 25, 2011, Senju and Kyorin filed a request for reexamination of Claims 1-3, 6, 8 and 9 of the '045 Patent with the United States Patent and Trademark Office. Plaintiffs did not request reexamination of Claims 4, 5 and 7. The request was granted on April 28, 2011, and assigned Reexamination Application Control No. 90/011509.

24. During the prosecution of Reexamination Application Control No. 90/011509, Plaintiffs submitted, for consideration by the United States Patent and Trademark Office, the prior art, other evidence, and arguments relied upon by the Court and Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al*., 07-779 (D. Del.) and the Court's decision in that case. Plaintiffs further canceled claims 1-3 and 8-11, amended claim 6 and added claims 12-16.

25. On October 25, 2011, the United States Patent and Trademark Office issued a reexamination certificate for the '045 Patent, canceling claims 1-3 and 8-11, and issuing

amended claim 6 and new claims 12-16 as patentable over the opinion, prior art, other evidence, and arguments from *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al*., 07-779 (D. Del.). The United States Patent and Trademark Office informed Plaintiffs of the publication of the '045 patent reexamination certificate on October 27, 2011.

26. Allergan is the holder of approved New Drug Application ("NDA") No. 22-548 that covers Zymaxid®, a 0.5% ophthalmic solution of gatifloxacin.

27. In conjunction with NDA No. 22-548, Allergan has listed the '045 Patent, the '283 patent and other patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") maintained by the U.S. Food and Drug and Administration ("FDA"). Allergan also informed FDA of the issuance of the '045 Patent reexamination certificate. Listing patents in the Orange Book obligates drug companies seeking approval to market a generic version of listed drug before the expiration of a listed patent to provide notice to the owner of the listed patent(s) and to the NDA holder with certain exceptions which do not apply to this case.

28. On information and belief, Apotex filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% with a Paragraph IV certification.

29. Upon information and belief, ANDA No. 203523 refers to, and relies upon, Allergan's NDA No. 22-548 and contains data that, according to Defendants, demonstrates the bioequivalence of the Defendants' proposed ANDA product to Allergan's Zymaxid® which is the subject of NDA No. 22-548.

30. In a letter dated January 13, 2012, Apotex advised Plaintiffs that it had filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% which is the subject of Allergan's NDA. Allergan received that letter on January 16, 2012.

31. The January 13, 2012 letter purports to advise Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that Apotex's ANDA No. 203523 had been filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.5% before the expiration of either the '045 Patent).

32. The January 13, 2012 letter does not state where the product of ANDA No. 203523 is to be manufactured and/or formulated.

COUNT 1

Infringement of Claims 6-7, 12, and 14-16

33. Paragraphs 1-38 are incorporated herein as set forth above.

34. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.5% in the United States before the expiration of the '045 Patent is an act of infringement of Claim 7 of the '045 Patent and Claims 6, 12 and 14-16 set forth on the '045 Patent reexamination certificate under 35 U.S.C. § 271(e)(2)(A).

35. Defendants are jointly and severally liable for infringement of those claims.

36. Apotex's participation in the submission of ANDA No. 203523 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Defendants were aware of the existence of the '045 Patent and the '045 Patent reexamination certificate and were aware that the filing of ANDA No. 203523 and certification with respect to the '045 Patent and the '045 Patent reexamination certificate constituted infringement. This is an exceptional case.

COUNT 2

Declaratory Judgment for Infringement of Claim 6 of the '045 Patent

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

39. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(2).

40. There is a concrete and immediate dispute between Plaintiffs and Defendants that creates an actual case or controversy permitting the Court to entertain Plaintiffs' request for declaratory relief pursuant to Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

41. Defendants' actions, including, but not limited to, the submission of ANDA No. 203523 and its continued defense of *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al*., 12-159 (D. Del.) indicate a refusal to change the course of their action.

42. Upon information and belief, Defendants will manufacture their proposed 0.5 w/v% ANDA product outside the United States.

43. Upon information and belief, Defendants manufacturing process for their proposed 0.5 w/v% ANDA product will use the method (including each step of the method) of Claim 6 of the '045 patent reexamination certificate.

44. As evidenced by Defendants ANDA, Defendants intend to import their proposed 0.5 w/v% ANDA product into the United States, without Plaintiffs' consent, and in violation of Plaintiffs' patent rights.

45. The importation of Defendants' proposed 0.5 w/v% ANDA product into the United States will infringe Plaintiffs' patent rights under 35 U.S.C. § 271(g).

46. Plaintiffs are entitled to a declaration that Apotex's submission of ANDA

No. 203523 to the FDA for gatifloxacin ophthalmic solution claimed in the '045 Patent, with the purpose of obtaining approval to engage in the commercial manufacture abroad and importation, use or sale of its 0.5 w/v% proposed ANDA product in United States prior to the expiration of the '045 Patent, infringes Claim 6 set forth in the '045 Patent reexamination certificate pursuant to 35 U.S.C. § 271(g).

47. 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

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed Claims 6, 12 and 14-16 of reexamined '045 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 203523 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale or sale within the United States and/or importation into the United States of the Defendants' gatifloxacin ophthalmic solution, 0.5% which is the subject of ANDA No. 203523, prior to the expiry of the '045 Patent, will infringe Claims 6, 12 and 14-16 of the reexamined '045 Patent;

B. A declaration pursuant to 35 U.S.C. § 2201 that Defendants' proposed commercial manufacture, use, offer for sale and/or sale of Defendants' gatifloxacin ophthalmic solution, 0.5% which is the subject of ANDA No. 203523 within the United States and/or its commercial importation into the United States, prior to the expiry of the '045 Patent, will infringe Claims 6, 12 and 14-16 of the reexamined '045 Patent;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 203523 under § 505(j) of the Federal Food, Drug and Cosmetic Act,

21 U.S.C. § 355(j), shall not be earlier than the expiration date of the '045 Patent or any extension thereof;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, servants, employees, licensees and representatives, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of Claims 6, 12 and 14-16 of the reexamined '045 Patent for the full term thereof;

E. A permanent injunction restraining and enjoining Defendants, its officers, agents, servants, employees, licensees and representatives, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '045 Patent and the '045 Patent reexamination certificate for the full term thereof;

F. A preliminary injunction restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '045 Patent and the '045 patent reexamination certificate for the full term thereof until such time as the Court issues a final decision on the merits;

G. An award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

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