

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD.,)	
KYORIN PHARMACEUTICAL CO., LTD.)	
AND ALLERGAN, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. _____
v.)	
)	
APOTEX INC. AND APOTEX CORP.,)	
)	
Defendants.)	

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 a declaratory judgment action seeking a declaration of infringement of United States Patent No. 6,333,045, as reexamined (“the ‘045 Patent”).

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 and its reexamination certificate 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. The claims of the '045 Patent have 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. The judgment entered on June 21, 2010, by the United States District Court for the District of Delaware in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.) is in abeyance pending the Court's decision with respect to the reopened record.

22. Plaintiffs intend to appeal any adverse judgment with respect to, at least, 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 decision, 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 reexamination certificate for the '045 Patent on October 27, 2011.

26. Allergan is the holder of approved New Drug Application ("NDA") Nos. 02-1493 and 22-548 that cover gatifloxacin ophthalmic solutions.

27. In conjunction with NDA Nos. 02-1493 and 22-548, Allergan has listed the '045 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 advised the FDA of the issuance of the reexamination certificate for the '045 Patent. Listing patents in the Orange Book obligates drug companies seeking approval to market a generic version of a 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, on July 19, 2007, Apotex filed ANDA No. 79-084. Apotex's ANDA No. 79-084 seeks FDA approval to market, sell and/or use gatifloxacin ophthalmic solution that is the subject of one or both of Allergan's NDAs.

29. In a letter dated October 17, 2007, Apotex advised Plaintiffs that it had filed ANDA No. 79-084 for gatifloxacin ophthalmic solution.

30. Within 45 days of receipt of the October 17, 2007 letter, Plaintiffs filed suit against Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.). Apotex has continuously defended that case to date, seeking an invalidity decision with respect to all asserted claims.

31. On August 19, 2011, Apotex received final approval from the FDA to market and sell gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084 in the United States.

32. On information and belief, Apotex has made, and continues to make, substantial preparation to market and sell a gatifloxacin ophthalmic solution in the United States.

COUNT 1

Declaratory Judgment of Infringement of Claims 6, 12, 13, 14, 15 and/or 16 of the '045 Patent under 35 U.S.C. § 271(e)(2)

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

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

35. 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.

36. Defendants filed a submission, ANDA No. 79-084, with the FDA pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act for gatifloxacin ophthalmic solution claimed in the '045 Patent, with the purpose of obtaining approval to engage in the commercial manufacture, use or sale of gatifloxacin ophthalmic solution prior to the expiration of the '045 Patent. Apotex received final approval of ANDA No. 79-084 from the FDA. The submission of ANDA No. 79-084 is an infringement of Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate pursuant to 35 U.S.C. 271(e)(2).

37. Defendants' actions, including, but not limited to, the submission of ANDA No. 79-084, the final approval of ANDA No. 79-084 and its continued defense of *Senju*

Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al., 07-779 (D. Del.) indicate a refusal to change the course of their action.

38. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of the gatifloxacin ophthalmic solution which is the subject of ANDA No. 79-084 prior to expiration of the '045 Patent will infringe Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate.

39. Plaintiffs are entitled to a declaration that Apotex's submission of ANDA No. 79-084 to the FDA for gatifloxacin ophthalmic solution claimed in the '045 Patent, with the purpose of obtaining approval to engage in the commercial manufacture, use or sale of gatifloxacin ophthalmic solution prior to the expiration of the '045 Patent, infringes Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate pursuant to 35 U.S.C. 271(e)(2).

40. 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.

COUNT 2

Declaratory Judgment of Infringement of Claims 6, 12, 13, 14, 15 and/or 16 of the '045 Patent under 35 U.S.C. § 271

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

42. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §271(a), (b) and/or (c).

43. 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.

44. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or use within the United States, and/or import into the United States the Defendants' gatifloxacin ophthalmic solution which is the subject of ANDA No. 79-084 prior to expiry of the '045 Patent.

45. Defendants' actions, including, but not limited to, the submission of ANDA No. 79-084, obtaining final approval of ANDA No. 79-084, and its continued defense of *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.) indicate a refusal to change the course of their action.

46. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of gatifloxacin ophthalmic solution which is the subject of ANDA No. 79-084 prior to expiration of the '045 Patent will infringe Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate.

47. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially imports, manufactures, uses, offers for sale or sells Defendants' gatifloxacin ophthalmic solution which is the subject of ANDA No. 79-084 within the United States, or induces or contributes to such conduct, Defendants will infringe Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate under 35 U.S.C. § 271(a), (b), and/or (c).

48. 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 declaration pursuant to 35 U.S.C. § 2201 that Apotex's submission of ANDA No. 79-084 to the FDA for gatifloxacin ophthalmic solution claimed in the '045 Patent, with the purpose of obtaining approval to engage in the commercial manufacture, use or sale of gatifloxacin ophthalmic solution prior to the expiration of the '045 Patent, infringes Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate pursuant to 35 U.S.C. 271(e)(2).

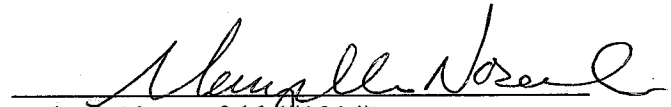
B. A declaration pursuant to 35 U.S.C. § 2201 that Defendants' proposed commercial manufacture, use, offer for sale and/or sale of Defendants' gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084 within the United States and/or its commercial importation into the United States, prior to the expiry of the '045 Patent, will infringe Claims 6, 12, 13, 14, 15 and/or 16 set forth in the '045 Patent reexamination certificate pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

C. 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 contributing to infringement of the '045 Patent for the full term thereof;

D. 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 contributing to infringement of the '045 Patent for the full term thereof until such time as the Court issues a final decision on the merits;

- E. An award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;
- F. Costs and expenses in this action; and
- G. Such other and further relief as the Court may deem just and proper.

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