IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD. KYORIN PHARMACEUTICAL CO., LTD. and ALLERGAN, INC.**,**	)	
Plaintiffs,	)	
v.	)	Case Action No. 11-cv-1059
HI-TECH PHARMACAL CO., INC.,	)	
Defendants.	)	

AMENDED 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 Hi-Tech Pharmacal Co., Inc. ("Hi-Tech" or "Defendant") as follows:

NATURE OF THE ACTION

1. This is an action for infringement of Reexamined United States Patent No. 6,333,045 ("the '045 Patent"), as reexamined, and United States Patent No. 5,880,283 ("the '283 Patent") under 35 U.S.C. §271 and declaration of infringement of those same patents.

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. Upon information and belief, Defendant is a Delaware corporation with a

place of business at 369 Bayview Avenue, Amityville, NY 11701.

6. Upon information and belief, Defendant imports, manufactures, sells and/or offers to sell numerous generic drug products in the United States, including Delaware.

JURISDICTION AND VENUE

7. This action arises under 35 U.S.C. Section 1, *et seq.* and 28 U.S.C. §2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant because Defendant has purposefully availed itself of the rights and benefits of Delaware law, regularly does and solicits business in Delaware, and derives substantial revenue from things used or consumed in Delaware.

9. This Court has personal jurisdiction over Defendant because of its continuous and systematic contacts with Delaware. On information and belief, Defendant 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; and is incorporated in Delaware.

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

BACKGROUND

11. The ‘045 Patent, entitled “Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin,” issued on December 25, 2001.

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

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

14. The claims of the ‘045 and ‘283 Patents have a statutory presumption of

validity that exists at all stages of a proceeding.

15. 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.).

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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 reexamination certificate for the '045 Patent on October 27, 2011. A copy of the '045 Patent and reexamination certificate is attached to this complaint as Exhibit A.

23. The '283 Patent, entitled "8-Alkoxyquinolonecarboxylic Acid Hydrate With Excellent Stability And Process For Producing The Same," issued on March 9, 1999. Claim 1 of the '283 Patent claims gatifloxacin sesquihydrate. A copy of the '283 Patent is attached to this complaint as Exhibit B.

24. Kyorin owns the entire right and interest in the '283 Patent.

25. Allergan is the exclusive licensee of the '283 Patent for ophthalmic uses.

26. Allergan is the holder of approved New Drug Application ("NDA") No. 21-493 that covers Zymar®, a 0.3% ophthalmic solution of gatifloxacin.

27. In conjunction with NDA No. 21-493, 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 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 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. Upon information and belief, Defendant, either directly or indirectly, submitted ANDA No. 203190 to the FDA for approval to market a gatifloxacin ophthalmic solution, 0.3%.

29. Upon information and belief, at least some gatifloxacin sesquihydrate is a component of the gatifloxacin API used to formulate the gatifloxacin ophthalmic solution, 0.3% that is the subject of ANDA No. 203190.

30. Upon information and belief, ANDA No. 203190 refers to, and relies upon, Allergan's NDA No. 21-493 and contains data that, according to Defendant, demonstrates the bioequivalence of the Defendant's proposed ANDA product to Allergan's Zymar® which is the subject of NDA No. 21-493.

31. Upon information and belief, Defendant researched and developed the gatifloxacin ophthalmic solution, 0.3% that is the subject of ANDA No. 203190; Defendant sought approval of ANDA No. 203190 from the FDA; and Defendant intends to engage in the commercial manufacture, marketing and sale of the gatifloxacin ophthalmic solution, 0.3% that is the subject of ANDA No. 203190, in the event that the FDA approves that ANDA.

32. In a letter dated September 12, 2011, received by Plaintiff Allergan on September 19, 2011, Defendant advised Senju, Kyorin and Allergan that it had filed ANDA No. 203190, seeking approval to market gatifloxacin ophthalmic solution, 0.3%.

33. The September 12, 2011 letter advises Plaintiffs pursuant to 21 U.S.C. §505(j)(2)(B) and 21 C.F.R. §§ 314.94 and 314.95 that ANDA No. 203190 was purportedly filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution

0.3% before the expiration of the ‘045 and ‘283 Patents.

34. Defendant in its detailed statement submitted with the September 12, 2011 letter (“Hi-Tech’s statement”) asserts that Claim 1 of the ‘283 patent will not be infringed. It also asserts that Claim 7 of the ‘045 patent is invalid.

35. Upon information and belief, Hi-Tech admits that the gatifloxacin ophthalmic solution 0.3% that is the subject of ANDA No. 203190 infringes Claim 7 of the ‘045 Patent, if valid.

36. Plaintiffs reserve the right to amend the complaint to add and/or substitute a different party for Defendant if, through discovery, Plaintiffs discover that a company other than Defendant is formulating, using, selling, offering to sale, manufacturing, and/or importing the gatifloxacin ophthalmic solution 0.3% and/or gatifloxacin sesquihydrate within the United States.

COUNT 1

Infringement of Claims 6, 7, 12, 13, 15, and 16 of the ‘045 Patent Under 35 U.S.C. § 271(e)(2)

37. Paragraphs 1-36 are incorporated herein as set forth above.

38. Defendant’s submission, directly or indirectly, of ANDA No. 203190 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.3% 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, 13, 15 and 16 of the ‘045 Patent reexamination certificate under 35 U.S.C. § 271(e)(2)(A).

39. Defendant’s submission of ANDA No. 203190, including its §505(j) allegations, to the FDA constitutes infringement of the ‘045 Patent under 35 U.S.C. § 271(e)(2)(A).

40. Defendant is liable for infringement of the ‘045 Patent.

41. Upon information and belief, Defendant was aware of the existence of the ‘045 Patent and was aware that the filing of ANDA No. 203190 and certification with respect to the ‘045 Patent constituted infringement of that patent. This is an exceptional case.

COUNT 2

Declaratory Judgment of Infringement of Claims 6, 7, 12, 13, 15 and 16 of the ‘045 Patent under 35 U.S.C. § 271

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

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

44. There is a concrete and immediate dispute between Plaintiffs and Defendant 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.

45. Defendant has 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 Defendant’s gatifloxacin ophthalmic solution which is the subject of ANDA No. 203190 prior to expiry of the ‘045 Patent.

46. Defendant’s actions, including, but not limited to, the submission of ANDA No. 203190 indicate a refusal to change the course of their action.

47. 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. 203190 prior to expiration of the ‘045 Patent will infringe Claims 6, 7, 12, 13, 15 and 16 of the ‘045 Patent.

48. Plaintiffs are entitled to a declaration that, if Defendant, prior to patent expiry, commercially imports, manufactures, uses, offers for sale or sells Defendant's gatifloxacin ophthalmic solution which is the subject of ANDA No. 203190 within the United States, or induces or contributes to such conduct, Defendant will infringe Claims 6, 7, 12, 13, 15 and 16 of the '045 Patent under 35 U.S.C. § 271(a), (b), (c) and/or (e).

49. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 3

Infringement of Claim 1 of the '283 Patent Under 35 U.S.C. 271(e)(2)

50. Paragraphs 1-36 are incorporated herein as set forth above.

51. On information and belief, Defendant, directly or indirectly, imports gatifloxacin containing gatifloxacin sesquihydrate into the United States and/or formulates its ANDA product in the United States using at least some gatifloxacin sesquihydrate as claimed in Claim 1 of the '283 Patent.

52. Defendant's submission of ANDA No. 203190 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.3%, formulated with at least some gatifloxacin sesquihydrate in the United States, before the expiration of the '283 Patent, was an act of infringement of Claim 1 of the '283 Patent under 35 U.S.C. § 271(e)(2)(A)

53. Defendant's submission of ANDA No. 203190 and its §505(j) allegations to the FDA constitutes infringement of Claim 1 of the '283 Patent under 35 U.S.C. § 271(e)(2)(A).

54. Defendant is liable for infringement of the ‘283 Patent.

55. Upon information and belief, Defendant was aware of the existence of the ‘283 Patent and was aware that the filing of ANDA No. 203190 and certification with respect to the ‘283 Patent constituted infringement of that patent. This is an exceptional case.

COUNT 4

Declaratory Judgment of Infringement of Claim 1 of the ‘283 Patent under 35 U.S.C. § 271

56. Paragraphs 1-36 and 50-55 are incorporated herein as set forth above.

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

58. There is a concrete and immediate dispute between Plaintiffs and Defendant 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.

59. Defendant has made, and will continue to make, substantial preparation in the United States to commercially manufacture, sell, offer to sell, and/or use within the United States, and/or import into the United States gatifloxacin containing gatifloxacin sesquihydrate for the purpose of formulating the Defendant’s gatifloxacin ophthalmic solution which is the subject of ANDA No. 203190, prior to expiry of the ‘283 Patent.

60. Defendant’s actions, including, but not limited to, the filing of ANDA No. 203190 indicate a refusal to change the course of their action.

61. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of gatifloxacin containing gatifloxacin sesquihydrate for the purpose of formulating Defendant’s gatifloxacin ophthalmic solution which is the subject of ANDA No.

203190 in the United States, prior to expiry of the '283 Patent, will infringe Claim 1 of the '283 Patent.

62. Plaintiffs are entitled to a declaration that, if Defendant, prior to patent expiry, commercially imports, manufactures, uses, offers for sale or sells gatifloxacin containing gatifloxacin sesquihydrate for the purpose of formulating Defendant's gatifloxacin ophthalmic solution which is the subject of ANDA No. 203190 within the United States, or induces or contributes to such conduct, Defendant will infringe Claim 1 of the '283 Patent under 35 U.S.C. § 271(a), (b), (c) and/or (e).

63. Plaintiffs will be irreparably harmed by Defendant's 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 Defendant has infringed Claims 6, 7, 12, 13, 15 and 16 of the '045 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 203190 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 Defendant's gatifloxacin ophthalmic solution, 0.3% which is the subject of ANDA No. 203190, prior to the expiry of the '045 Patent, will infringe Claims 6, 7, 12, 13, 15 and 16 of the '045 Patent;

B. A declaration pursuant to 35 U.S.C. § 2201 that Defendant's proposed commercial manufacture, use, offer for sale and/or sale of Defendant's gatifloxacin ophthalmic solution, 0.3% which is the subject of ANDA No. 203190 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, 7, 12, 13, 15 and 16 of the '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. 203190 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 restraining and enjoining Defendant, 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 for the full term thereof;

E. A judgment that Defendant has infringed Claim 1 of the '283 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 203190 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale and/or sale of gatifloxacin containing gatifloxacin sesquihydrate within the United States and/or its commercial importation into the United States for the purpose of formulating Defendant's gatifloxacin ophthalmic solution, 0.3% which is the subject of ANDA No. 203190, prior to the expiry of the '283 Patent, will infringe Claim 1 of the '283 Patent;

F. A declaration pursuant to 35 U.S.C. § 2201 that Defendant's proposed commercial manufacture, use, offer for sale and/or sale of gatifloxacin containing gatifloxacin sesquihydrate within the United States and/or its commercial importation into the United States for the purpose of formulating Defendant's gatifloxacin ophthalmic solution, 0.3% which is the subject of ANDA No. 203190, prior to the expiry of the '283 Patent, will infringe Claim 1 of the '283 Patent;

G. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 203190 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 '283 Patent or any extension thereof;

H. A permanent injunction restraining and enjoining Defendant, 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 '283 Patent for the full term thereof;

I. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

J. An award of costs and expenses in this action; and

K. Such other and further relief as the court may deem just and proper.

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November 9, 2011

CERTIFICATE OF SERVICE

I hereby certify that on November 9, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Adam W. Poff, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP

I further certify that I caused copies of the foregoing document to be served on November 9, 2011, upon the following in the manner indicated:

Adam W. Poff, Esquire — *VIA ELECTRONIC MAIL*
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/s/ Maryellen Noreika

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