IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD. and ALLERGAN, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 11-439 (UNA)
LUPIN LIMITED and LUPIN PHARMACEUTICALS, 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 amended complaint against Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharma") (collectively "Defendants") as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 6,333,045 ("the '045 Patent") and United States Patent No. 5,880,283 ("the '283 Patent") under 35 U.S.C. §271(e)(2) 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 Lupin Ltd. is an Indian corporation with a place of business at B/4 Laxmi Towers, 5th Floor, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India.

6. Upon information and belief, defendant Lupin Ltd. imports into and/or supplies to the United States numerous generic drug products.

7. Upon information and belief, defendant Lupin Pharma is a Virginia Corporation, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

8. Upon information and belief, defendant Lupin Pharma distributes and/or sells generic drug products throughout the United States, including Delaware.

9. Upon information and belief, Lupin Pharma is a United States agent for Lupin Ltd. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

10. Upon information and belief, Lupin Pharma is also a United States marketing and sales agent for Lupin Ltd.

11. Upon information and belief, after receiving FDA approval of an Abbreviated New Drug Application ("ANDA"), Lupin Ltd. manufactures and supplies an approved generic product or active pharmaceutical ingredient ("API") to Lupin Pharma, which then formulates the API into an approved generic product and/or markets and/or sells an approved product throughout the United States, including Delaware.

12. Upon information and belief, Lupin Pharma is a wholly owned subsidiary of Lupin Ltd.

13. Upon information and belief Lupin Pharma is the alter ego of Lupin Ltd.

14. Upon information and belief, defendant Lupin Ltd. through its wholly owned subsidiary and agent, Lupin Pharma, offers for sale and sells numerous generic drugs manufactured and/or imported and/or supplied by Lupin Ltd. throughout the United States, including Delaware.

JURISDICTION AND VENUE

15. 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).

16. This Court has personal jurisdiction over the Defendants because each 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.

17. This Court has personal jurisdiction over Defendant Lupin Ltd. because of its continuous and systematic contacts with Delaware. On information and belief, Lupin Ltd., directly or through its wholly owned subsidiary and agent, Lupin Pharma, 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, e.g., *Cephalon Inc. v. Lupin Limited*, 10-cv-210 (D. Del.);

Warner Chilcott Company LLC v. Lupin Limited, 09-cv-673 (D. Del.); *Forest Laboratories Inc. et al v. Lupin Pharmaceuticals Inc.*, 08-cv-0021 (D. Del.)

18. This Court has personal jurisdiction over Defendant Lupin Pharma because of its continuous and systematic contacts with Delaware. On information and belief, Lupin Pharma, 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, e.g., *Cephalon Inc. v. Lupin Limited*, 10-cv-210 (D. Del.); *Warner Chilcott Company LLC v. Lupin Limited*, 09-cv-673 (D. Del.); *Forest Laboratories Inc. et al v. Lupin Pharmaceuticals Inc.*, 08-cv-0021 (D. Del.)

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

BACKGROUND

20. The '045 Patent, entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin," issued on December 25, 2001. A copy of the '045 Patent is attached to this complaint as Exhibit A.

21. Senju and Kyorin jointly own the entire right and interest in the '045 Patent.

22. Allergan is the exclusive licensee of the '045 Patent for ophthalmic uses.

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. 02-1493 that covers Zymar®, a 0.3% ophthalmic solution of gatifloxacin.

27. In conjunction with NDA No. 02-1493, 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"). 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, on April 8, 2010, Lupin Ltd. filed Drug Master File ("DMF") No. 23552 for gatifloxacin.

29. Upon information and belief, Lupin Ltd., either directly or indirectly through its wholly owned subsidiary and agent Lupin Pharma, submitted ANDA No. 202-709 to the FDA for approval to market a gatifloxacin ophthalmic solution, 0.3%.

30. Upon information and belief, Lupin Ltd. manufactured and continues to manufacture, at least some, gatifloxacin sesquihydrate.

31. Upon information and belief, Lupin Ltd. produces at least some gatifloxacin sesquihydrate as part of its manufacture of gatifloxacin API pursuant to DMF No.

23552, which is subsequently used to formulate the gatifloxacin ophthalmic solution, 0.3% that is the subject of ANDA No. 202-709.

32. Upon information and belief, Lupin Ltd. filed DMF No. 23552 for gatifloxacin with the intent to supply gatifloxacin, including at least some gatifloxacin sesquihydrate, to Lupin Pharma to prepare the gatifloxacin ophthalmic solution 0.3% that is the subject of ANDA No. 202-709 with the intent to market the solution in the United States before the expiration of the '045 and '283 Patents.

33. Upon information and belief, ANDA No. 202-709 refers to, and relies upon, Allergan's NDA No. 02-1493 and contains data that, according to Defendants, demonstrates the bioequivalence of the Defendants' proposed ANDA product to Allergan's Zymar® which is the subject of NDA No. 02-1493.

34. Upon information and belief, Lupin Ltd. and Lupin Pharma collaborated in the research and development of Lupin Ltd.'s ANDA No. 202-709 for gatifloxacin ophthalmic solution, 0.3%; they continue to collaborate in the submission and seeking approval of ANDA No. 202-709 from the FDA; and they intend to collaborate in the commercial manufacture, marketing and sale of the gatifloxacin ophthalmic solution, 0.3% that is the subject of ANDA No. 202-709, in the event that the FDA approves that ANDA.

35. Upon information and belief, the acts of Lupin Ltd, complained of herein, were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Lupin Pharma.

36. In a letter dated April 7, 2011, Lupin Ltd. advised Senju, Kyorin and Allergan that it had filed ANDA No. 202-709, seeking approval to market gatifloxacin ophthalmic solution, 0.3%.

37. The April 7, 2011 letter advises Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that ANDA No. 202-709 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.

38. Lupin Ltd. in its detailed statement submitted with the April 7, 2011, letter ("Lupin Ltd.'s statement") asserts that Claim 1 of the '283 Patent will not be infringed and that Claim 7 of the '045 Patent is not infringed. It also asserts Claims 1-3, 7 and 9 of the '045 are invalid.

39. Upon information and belief, Lupin Ltd. admits that the gatifloxacin ophthalmic solution 0.3% that is the subject of ANDA No. 202-709 infringes Claims 1-3 and 9 of the '045 Patent, if valid.

40. The claims of the '045 and '283 Patents have a statutory presumption of validity that exists at all stages of a proceeding.

41. 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.)

42. 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 were invalid as obvious.

43. 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.

44. 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.

45. Should 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.), find Claim 7 valid in light of the reopened record, Claims 1-3 and 9 of the '045 Patent are also valid on the basis of the unexpected results achieved from the method claimed in Claim 7 of the '045 Patent.

46. Plaintiffs will appeal any adverse judgment with respect to, at least, Claims 1-3, 7 and 9 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.

47. 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. The request was granted on April 28, 2011, and assigned Reexamination Application No. 90/011509.

48. The United States Patent and Trademark Office sent Senju and Kyorin a non-final office action in Reexamination Application No. 90/011509 on April 28, 2011, rejecting Claims 1-3, 6, 8 and 9 of the '045 patent. Senju and Kyorin will file a response to the office action, amending the claims and traversing the rejections.

49. Plaintiffs reserve the right to amend the complaint to add and/or substitute a different party for Defendants if, through discovery, Plaintiffs discover that a company other than Lupin Ltd. and/or Lupin Pharma 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 1-3, 7 and 9 of the '045 Patent Under 35 U.S.C. § 271(e)(2)

50. Paragraphs 1-49 are incorporated herein as set forth above.

51. Lupin Ltd.'s submission, directly or indirectly through its wholly owned subsidiary and agent Lupin Pharma, of ANDA No. 202-709 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 was an act of infringement of Claims 1-3, 7 and 9 under 35 U.S.C. § 271(e)(2)(A) of the '045 Patent.

52. Defendants are jointly and severally liable for infringement of the '045 Patent. Upon information and belief, Lupin Pharma participated in Lupin Ltd.'s submission of ANDA No. 202-709 to the FDA.

53. Lupin Pharma's participation in the submission of ANDA No. 202-709 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '045 Patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Defendants were aware of the existence of the '045 Patent and were aware that the filing of ANDA No. 202-709 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 the '045 Patent under 35 U.S.C. § 271

55. Paragraphs 1-54 are incorporated herein as set forth above.

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

57. 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.

58. 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. 202-709 prior to expiry of the '045 Patent.

59. Defendants' actions, including, but not limited to, the submission of ANDA No. 202-709 indicate a refusal to change the course of their action.

60. 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. 202-709 prior to expiration of the '045 Patent will infringe Claims 1-3, 7 and 9 of the '045 Patent.

61. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially import, manufacture, use, offer for sale or sell Defendants' gatifloxacin ophthalmic solution which is the subject of ANDA No. 202-709 within the United States, or induce or contribute to such conduct, Defendants will infringe Claims 1-3, 7 and 9 of the '045 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

62. 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 3
Infringement of Claim 1 of the '283 Patent Under 35 U.S.C. 271(e)(2)

63. Paragraphs 1-49 are incorporated herein as set forth above.

64. On information and belief, Lupin Ltd., directly or indirectly through its wholly owned subsidiary Lupin Pharma, 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.

65. Lupin Ltd.'s submission of ANDA No. 202-709 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)

66. Defendants are jointly and severally liable for infringement of the '283 Patent. Upon information and belief, Lupin Pharma participated in Lupin Ltd.'s submission of ANDA No. 202-709 to the FDA.

67. Lupin Pharma's participation in the submission of ANDA No. 202-709 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of Claim 1 of the '283 Patent under 35 U.S.C. § 271(e)(2)(A).

68. Upon information and belief, Defendants were aware of the existence of the '283 Patent and were aware that the filing of ANDA No. 202-709 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 the '283 Patent under 35 U.S.C. § 271

69. Paragraphs 1-49 and 63-68 are incorporated herein as set forth above.

70. 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).

71. 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.

72. Defendants have 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 Defendants' gatifloxacin ophthalmic solution which is the subject of ANDA No. 202-709, prior to expiry of the '283 Patent.

73. Defendants' actions, including, but not limited to, the filing of ANDA No. 202-709 indicate a refusal to change the course of their action.

74. 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 Defendants' gatifloxacin ophthalmic solution which is the subject of ANDA No. 202-709 in the United States, prior to expiry of the '283 Patent, will infringe Claim 1 of the '283 Patent.

75. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially import, manufacture, use, offer for sale or sell gatifloxacin containing gatifloxacin sesquihydrate for the purpose of formulating Defendants' gatifloxacin ophthalmic solution which is the subject of ANDA No. 202-709 within the United States, or induce or contribute to such conduct, Defendants will infringe Claim 1 of the '283 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

76. 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 1-3, 7 and 9 of the '045 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 202-709 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, 0.3% which is the subject of ANDA No. 202-709, prior to the expiry of the '045 Patent, will infringe Claims 1-3, 7 and 9 of the '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, 0.3% which is the subject of ANDA No. 202-709 within the United States and/or its commercial importation into the United States, prior to the expiry of the '045 Patent, will infringe Claims 1-3, 7 and 9 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. 202-709 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 1-3, 7 and 9 of the '045 Patent for the full term thereof;

E. A judgment that Defendants have infringed Claim 1 of the '283 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 202-709 under the Federal Food, Drug,

and Cosmetic Act, and that the commercial manufacture, use, offer for sale and/or sale of gatifloxacin within the United States and/or its commercial importation into the United States for the purpose of formulating Defendants' gatifloxacin ophthalmic solution, 0.3% which is the subject of ANDA No. 202-709, prior to the expiry of the '283 Patent, will infringed Claim 1 of the '283 Patent;

F. A declaration pursuant to 35 U.S.C. § 2201 that Defendants' proposed commercial manufacture, use, offer for sale and/or sale of gatifloxacin sesquihydrate within the United States and/or its commercial importation into the United States for the purpose of formulating Defendants' gatifloxacin ophthalmic solution, 0.3% which is the subject of ANDA No. 202-709, 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. 202-709 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, 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 Claim 1 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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