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. _____
STRIDES, INC. and AGILA SPECIALITIES PRIVATE LIMITED,	)	
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 Strides, Inc. ("Strides") and Agila Specialties Private Limited ("Agila") (collectively "Defendants") as follows:

Nature of the Action

1. This is an action for infringement and declaratory judgment of infringement of Reexamined United States Patent No. 6,333,045 ("the '045 patent"). The infringement action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to commercially manufacture and sell a generic copy of Allergan's very successful Zymar® (0.3 w/v % gatifloxacin) and Zymaxid® (0.5 w/v % gatifloxacin) ophthalmic solutions, prior to the expiration of 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 6, Kanda Surugadai 4-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 Strides is a New Jersey corporation with a place of business at 201 South Main Street, Suite #3, Lambertville, NH 08530.

6. On information and belief, Strides is the U.S. agent for Agila. On information and belief, Strides imports, distributes, manufactures, markets, offers for sale and/or sells generic pharmaceutical products throughout the United States, including the State of Delaware.

7. On information and belief, defendant Strides imports, distributes, markets, offers for sale and/or sells numerous generic drugs manufactured and supplied by Agila throughout the United States, including the State of Delaware.

8. On information and belief, defendant Agila is a corporation organized under the laws of India, with a place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560076 India.

9. On information and belief, defendant Agila is engaged in the distribution, manufacture, marketing, offering for sale, and/or sale of generic pharmaceutical products throughout the United States, including the State of Delaware.

10. On information and belief, Agila, directly or indirectly through its U.S. agent, Strides, submitted Abbreviated New Drug Applications ("ANDA") to the FDA, seeking approval to commercially manufacture, use or sell, in the United States, generic gatifloxacin ophthalmic solutions prior to the expiration of the '045 patent.

11. On information and belief, Defendants are formulating and/or planning to formulate gatifloxacin ophthalmic solutions to be marketed and sold in the United States. Plaintiffs reserve the right to amend the complaint to substitute a different party(ies) for Defendants if, through discovery, Plaintiffs discover that person(s) other than Defendants are formulating and/or marketing and/or selling the gatifloxacin ophthalmic solutions that are the subject of Defendants' ANDAs.

12. On information and belief, the acts of each Defendant complained of herein were done with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of the other Defendant.

13. Upon information and belief, Defendants act in concert with respect to collaborating in the development, marketing, sale, and obtaining regulatory approval of generic copies of branded pharmaceutical products, including gatifloxacin ophthalmic solutions.

Jurisdiction and Venue

14. 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).

15. This Court has personal jurisdiction over Defendants because of their continuous and systematic contacts with Delaware. On information and belief, Defendants directly or indirectly purposefully offer to sell, sell, market, distribute, and/or manufacture goods, including generic pharmaceutical products, for sale in the United States and Delaware; derive substantial revenue from things used or consumed in Delaware, regularly do business and solicit business in Delaware; and have admitted and/or consented to jurisdiction in this Court, including, *e.g., Aventis Pharma S.A. et al v. Strides Inc. et al.,* 11-cv-1121 (D. Del.).

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

Background

17. The '045 patent, entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin," issued on December 25, 2001. A certified copy of the '045 patent, its reexamination certificate, and certificate of correction is attached to this complaint as Exhibit A. The reexamination certificate issued on October 25, 2011.

18. Senju and Kyorin jointly own the entire right, title, and interest in the '045 patent.

19. Allergan is the exclusive licensee of the '045 patent for ophthalmic uses in the United States.

20. Each claim of the '045 patent has a statutory presumption of validity that exists at all stages of a proceeding.

21. On information and belief, Defendants' business activities include the importation, distribution, manufacturing, marketing, offering for sale, and/or selling of generic pharmaceutical products in the United States generally and the State of Delaware specifically.

22. On information and belief, as part of their regularly conducted business activities, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

0.3 w/v% Gatifloxacin Ophthalmic Solution

23. Allergan is the holder of approved New Drug Application ("NDA") No. 02-1493 that covers Zymar®, a 0.3 w/v% gatifloxacin ophthalmic solution.

24. In conjunction with NDA No. 02-1493, Allergan has listed the '045 patent 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 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.

25. On information and belief, Defendants filed ANDA No. 204897, with a Paragraph IV certification, for approval to commercially market a 0.3 w/v% gatifloxacin ophthalmic solution.

26. Upon information and belief, ANDA No. 204897 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.

27. In a letter dated March 27, 2013, Defendants provided notice to Plaintiffs that they had submitted to the FDA ANDA No. 204897 for approval to commercially market a generic copy of the 0.3 w/v% gatifloxacin ophthalmic solution that is the subject of Allergan's NDA No. 02-1493. Plaintiffs received that letter on April 2, 2013.

28. The March 27, 2013, Paragraph IV notice letter purports to advise Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that ANDA No. 204897 was filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.3% before the expiration of the '045 patent.

29. Defendants were necessarily aware of the patent-in-suit when they filed ANDA No. 204897 containing the Paragraph IV certification with the FDA.

30. The March 27, 2013, Paragraph IV notice letter does not state where the product of ANDA No. 204897 is to be manufactured and/or formulated.

31. Upon information and belief, the gatifloxacin API used to manufacture the 0.3 w/v% gatifloxacin product that is the subject of ANDA No. 204897 contains, at least some, gatifloxacin sesquihydrate.

32. Plaintiffs are commencing this action within forty-five days of the date they received Defendants' March 27, 2013, Paragraph IV notice letter for ANDA No. 204897 containing the Paragraph IV certification.

0.5 w/v% Gatifloxacin Ophthalmic Solution

33. Allergan is the holder of approved NDA No. 22-548 that covers Zymaxid®, a 0.5 w/v% gatifloxacin ophthalmic solution.

34. In conjunction with NDA No. 22-548, Allergan has listed the '045 patent 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 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.

35. On information and belief, Defendants filed ANDA No. 204896, with a Paragraph IV certification, for approval to commercially market a 0.5 w/v% gatifloxacin ophthalmic solution.

36. Upon information and belief, ANDA No. 204896 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.

37. In a letter dated March 27, 2013, Defendants provided notice to Plaintiffs that they had submitted to the FDA ANDA No. 204896 for approval to commercially market a generic copy of the 0.5 w/v % gatifloxacin ophthalmic solution that is the subject of Allergan's NDA No. 22-548. Plaintiffs received that letter on April 2, 2013.

38. The March 27, 2013, Paragraph IV notice letter purports to advise Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that ANDA No. 204896 was filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.5% before the expiration of the '045 patent.

39. Defendants were necessarily aware of the patent-in-suit when they filed ANDA No. 204897 containing the Paragraph IV certification with the FDA.

40. The March 27, 2013, Paragraph IV notice letter does not state where the product of ANDA No. 204896 is to be manufactured and/or formulated.

41. Upon information and belief, the gatifloxacin API used to manufacture the 0.5 w/v% gatifloxacin product that is the subject of ANDA No. 204896 contains, at least some, gatifloxacin sesquihydrate.

42. Plaintiffs are commencing this action within forty-five days of the date they received Defendants' March 27, 2013, Paragraph IV notice letter of ANDA No. 204896 containing the Paragraph IV certification.

COUNT 1
Infringement of Claims 6, 12-13, and 15-16 of the '045 patent by ANDA No. 204897

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

44. Defendants' submission of ANDA No. 204897 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 Claims 6, 12, 13, 15 and 16 of the '045 patent under 35 U.S.C. § 271(e)(2)(A).

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

46. Defendants' submission of ANDA No. 204897 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

47. On information and belief, Defendants will financially benefit from the submission and, if received, approval of ANDA No. 204897.

48. Upon information and belief, Defendants were aware of the existence of the '045 patent and were aware that the filing of ANDA No. 204897 and a Paragraph IV certification with respect to the '045 patent constituted infringement of the '045 patent. This is an exceptional case.

COUNT 2

Infringement of Claims 6, 12, and 14-16 of the '045 patent by ANDA No. 204896

49. Paragraphs 1-48 are incorporated herein as set forth above.

50. Defendants' submission of ANDA No. 204896 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 Claims 6, 12, 14, 15 and 16 of the '045 patent under 35 U.S.C. § 271(e)(2)(A).

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

52. Defendants' participation in the submission of ANDA No. 204896 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

53. On information and belief, Defendants will financially benefit from the submission and, if received, approval of ANDA No. 204896.

54. Upon information and belief, Defendants were aware of the existence of the '045 patent and were aware that the filing of ANDA No. 204896 and a Paragraph IV certification with respect to the '045 patent constituted infringement of the '045 patent. This is an exceptional case.

COUNT 3

Declaratory Judgment of Infringement of Claims 6, 12-13, and 15-16 of the '045 patent

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/or (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 gatifloxacin ophthalmic solution that is the subject of ANDA No. 204897 prior to the expiration of the '045 patent.

59. Defendants' actions, including, but not limited to, the submission of ANDA No. 204897, indicate a refusal to change their course of action.

60. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of gatifloxacin ophthalmic solution that is the subject of ANDA No. 204897 prior to the expiration of the '045 patent will infringe Claims 6, 12, 13, 15, and 16 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 the gatifloxacin ophthalmic solution that is the subject of ANDA No. 204897 within in the United States or import it into the United States, they will infringe Claims 6, 12, 13, 15 and 16.

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 4
Declaratory Judgment of Infringement of Claims 6, 12, 14-16 of the '045 patent

63. Paragraphs 1-62 are incorporated herein as set forth above.

64. 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).

65. 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.

66. 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 gatifloxacin ophthalmic solution that is the subject of ANDA No. 204896 prior to the expiration of the '045 patent.

67. Defendants' actions, including, but not limited to, the submission of ANDA No. 204896, indicate a refusal to change their course of action.

68. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of gatifloxacin ophthalmic solution that is the subject of ANDA No. 204896 prior to the expiration of the '045 patent will infringe Claims 6, 12, 14, 15, and 16 of the '045 patent.

69. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially import, manufacture, use, offer for sale, or sell the gatifloxacin ophthalmic solution that is the subject of ANDA No. 204896 within in the United States or import it into the United States, they will infringe Claims 6, 12, 14, 15 and 16.

70. 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, 13, 15 and 16 of the '045 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 204897 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. 204897, prior to the expiry of the '045 patent, will infringe Claims 6, 12, 13, 15 and 16 of the '045 patent;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 204897 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;

C. A judgment that Defendants have infringed Claims 6, 12, 14, 15, and 16 of the '045 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 204896 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. 204896, prior to the expiry of the '045 patent, will infringe Claims 6, 12, 14, 15 and 16 of the '045 patent;

D. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 204896 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;

E. 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 and 12-16 of the '045 patent for the full term thereof;

F. A declaration that Defendants commercial manufacture, sale, offer to sell, use in the United States, or importation into the United States, of the 0.3 w/v% gatifloxacin ophthalmic solution that is the subject of ANDA No. 204897 prior to the expiration of the '045 patent will infringe Claims 6, 12, 13, 15 and 16 of the '045 patent.

G. A declaration that Defendants' commercial manufacture, sale, offer to sell, use in the United Sates, or importation into the United States, of the 0.5 w/v% gatifloxacin

ophthalmic solution that is the subject of ANDA No. 204896 prior to the expiration of the '045 patent will infringe Claims 6, 12, 14, 15 and 16 of the '045 patent.

H. A permanent injunction, pursuant to 35 U.S.C. § 283, 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 and 12-16 of the '045 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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