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. _____
ACTAVIS INC., ACTAVIS PHARMA INC., and WATSON LABORATORIES, INC.	)	
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 Actavis Inc. ("Actavis"), Actavis Pharma, Inc. ("API") and Watson Laboratories, Inc. ("Watson") (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").

2. The infringement action arises out of Defendants' submission of an Abbreviated New Drug Application ("ANDA") seeking approval to commercially manufacture and sell a generic copy of Allergan's very successful Zymaxid® (0.5 w/v % gatifloxacin) ophthalmic solution, prior to the expiration of the '045 patent.

The Parties

3. 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.

4. 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.

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

6. On information and belief, defendant Actavis is a Nevada corporation with a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054.

7. On information and belief, defendant API is a Delaware corporation with a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054.

8. On information and belief, defendant Watson is a Nevada corporation with a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054.

9. On information and belief, Watson imports, distributes, manufactures, markets, offers for sale and/or sells generic pharmaceutical products throughout the United States, including the State of Delaware.

10. On information and belief, Watson is the wholly-owned subsidiary of Actavis and is controlled by Actavis.

11. On information and belief, Defendants submitted, collaborated and/or acted in concert in the preparation of ANDA No. 206478.

12. On information and belief, defendant Watson, directly and/or indirectly through API, imports, distributes, markets, offers for sale and/or sells numerous generic drugs manufactured and supplied by Watson throughout the United States, including the State of Delaware.

13. On information and belief, defendant Watson holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0001463. On information and belief, Watson holds a Distributor/Manufacturer License for Controlled Substances Registration from the State of Delaware under License No. DS0499. On information and belief, Watson, will either directly or indirectly through, and in concert with Actavis and API, manufacture, distribute, market, offer to sell and/or sell the 0.5 w/v% gatifloxacin ophthalmic solution that is the subject of Abbreviated New Drug Application ("ANDA") No. 206478 in Delaware under the auspices of these licenses.

14. On information and belief, defendant API holds Pharmacy Wholesale Licenses from the State of Delaware under License Nos. A4-0000627 and A4-0000683, A4-0001998. On information and belief, API holds a Distributor/Manufacturer License for Controlled Substances Registration from the State of Delaware under License Nos. DS0503 and DS0319. On information and belief, API, will either directly or indirectly through, and in concert with Actavis and Watson, manufacture, distribute, market, offer to sell and/or sell the 0.5 w/v% gatifloxacin ophthalmic solution that is the subject of Abbreviated New Drug Application ("ANDA") No. 206478 in Delaware under the auspices of these licenses.

15. On information and belief, Watson, directly or indirectly, submitted ANDA No. 206478 to the United States Food and Drug Administration, seeking approval to commercially manufacture, use or sell, in the United States, a generic 0.5 w/v% gatifloxacin ophthalmic solution prior to the expiration of the '045 patent.

16. On information and belief, Defendants are formulating and/or planning to formulate 0.5 w/v% gatifloxacin ophthalmic solutions and will market and sell them 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' ANDA.

17. On information and belief, the acts of Defendants 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 Defendants.

18. Upon information and belief, Defendants acted in concert, and/or will act in concert, with respect to collaborating in the development, marketing, sale, and obtaining regulatory approval of generic copies of branded pharmaceutical products, including 0.5 w/v% gatifloxacin ophthalmic solutions.

Jurisdiction and Venue

19. Paragraphs 1-18 are incorporated herein as set forth above.

20. This action arises under 35 U.S.C. Section 1, *et seq.*

21. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

22. 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.

23. Watson has been sued for patent infringement in this district and purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court. *See, e.g., Merck & Co. v. Watson Laboratories, Inc.*, Civil Action No. 05-658.

24. API, Actavis, and Watson have purposefully availed itself of the rights and benefits of this Court by having cases transferred from other districts to this Court. *See, e.g., Bayer Pharma AG v. Watson Laboratories, Inc.*, Civil Action No. 14-760. API, Actavis and Watson argued in that case the case should be transferred from District of New Jersey to the District of Delaware because there were already Hatch-Waxman cases pending in the District of Delaware with respect to the same NDA and the same patents and because the Judge in the District of Delaware already had familiarity with the patents and technology in that case. Those facts are equally applicable here. There are multiple related cases to this litigation pending in the District of Delaware, and involving the same patent and NDA. The Honorable Judge Sue Robinson of the District of Delaware has familiarity with the technology and patent-at-issue in this case.

25. Actavis has been sued for patent infringement in this district and purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court. *See, e.g., Sunovion Pharmaceuticals v. Watson Pharmaceuticals, Inc.,* Civil Action No. 12-993.

26. This Court has personal jurisdiction over Defendants because they have, directly or indirectly, availed themselves of the benefit of the State of Delaware's Pharmacy and Controlled Substances licensure programs to obtain authorization to manufacture, distribute, market, offer for sale and/or sell generic pharmaceutical products in Delaware, including the 0.5 w/v% gatifloxacin ophthalmic solution that is the subject of ANDA No. 206478.

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

Background

28. 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 certificates, and certificates of correction are attached to this complaint as Exhibit A. The reexamination certificate issued on October 25, 2011.

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

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

31. The claims of the reexamined '045 patent were asserted in *Senju Pharma. Co. Ltd. v. Lupin Ltd.*, 11-cv-271 (D. Del.) against Lupin Ltd., Lupin Pharmaceuticals, Inc. and Hi-Tech Pharmacal Co., Inc.

32. On August 9, 2013, the United States District Court for the District of Delaware ruled the asserted claims of the '045 patent reexamination certificate to be infringed by the Defendants in Civil Action No. 11-cv-271, but invalid as obvious.

33. The August 9, 2013, district court decision is presently on appeal before the Court of Appeals for the Federal Circuit. Oral argument was held on May 7, 2014, and a decision is expected later that year.

34. 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.

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

0.5 w/v% Gatifloxacin Ophthalmic Solution

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

37. 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.

38. On information and belief, Defendants submitted, directly or indirectly, ANDA No. 206478 to the FDA with a Paragraph IV certification for approval to commercially market a 0.5 w/v% gatifloxacin ophthalmic solution.

39. Upon information and belief, ANDA No. 206478 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.

40. In a letter dated May 30, 2014, Defendants provided notice to Plaintiffs that they had submitted to the FDA ANDA No. 206478 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. Plaintiff Senju received that letter on June 2, 2014. Plaintiffs Kyron and Allergan received the notice letter thereafter.

41. The May 30, 2014, 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. 206478 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.

42. Defendants were necessarily aware of the '045 patent when they submitted ANDA No. 206478 containing the Paragraph IV certification with the FDA.

43. Plaintiffs are commencing this action within forty-five days of the date they received Defendants' May 30, 2014, Paragraph IV notice letter of ANDA No. 206478 containing the Paragraph IV certification.

COUNT 1
Infringement of Claims 6, 12, and 14-16 of the '045 patent by ANDA No. 206478

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

45. Defendants' submission of ANDA No. 206478 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution, 0.5 w/v%, 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).

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

47. Defendants' participation in the submission of ANDA No. 206478 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

48. On information and belief, Defendants will financially benefit from the submission and, if received, approval of ANDA No. 206478.

49. Upon information and belief, Defendants were aware of the existence of the '045 patent and were aware that the submission of ANDA No. 206478 and a Paragraph IV certification with respect to the '045 patent to the FDA constituted infringement of the '045 patent reexamination certificate.

COUNT 2

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

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

51. 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).

52. 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.

53. 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 0.5 w/v% gatifloxacin ophthalmic solution that is the subject of ANDA No. 206478 prior to the expiration of the '045 patent.

54. Defendants' actions indicate a refusal to change their course of action.

55. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of 0.5 w/v% gatifloxacin ophthalmic solution that is the subject of ANDA No. 206478 prior to the expiration of the '045 patent will infringe Claims 6, 12, 14, 15, and 16 of the '045 patent.

56. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially import, manufacture, use, offer for sale, or sell the 0.5 w/v% gatifloxacin ophthalmic solution that is the subject of ANDA No. 206478 within in the United States or import it into the United States, they will infringe Claims 6, 12, 14, 15 and 16 of the '045 patent reexamination certificate.

57. 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
Declaratory Judgment for Infringement of Claim 6 of the '045 Patent

58. Paragraphs 1-57 are incorporated herein as set forth above.

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

60. 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.

61. Defendants' actions indicate a refusal to change the course of their action.

62. Upon information and belief, Defendants will manufacture their proposed 0.5 w/v% gatifloxacin ophthalmic solution outside the United States.

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

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

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

66. Plaintiffs are entitled to a declaration that Defendants' submission of ANDA No. 206478 to the FDA for their 0.5 w/v% gatifloxacin ophthalmic solution, with the purpose of obtaining approval to engage in the commercial manufacture abroad and importation, use or sale of their proposed 0.5 w/v% gatifloxacin ophthalmic solution in United States prior to the expiration of the '045 patent, infringes Claim 6 as set forth in the '045 patent reexamination certificate pursuant to 35 U.S.C. § 271(g).

67. 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, 14, 15 and 16 of the '045 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 206478 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. 206478, prior to the expiry of the '045 patent, will infringe Claims 6, 12, 14, 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. 206478 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 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, 14-16 of the '045 patent for the full term thereof;

D. 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. 206478 prior to the expiration of the '045 patent will infringe Claims 6, 12, 14, 15 and 16 of the '045 patent.

E. 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. 206478 prior to the expiration of the '045 patent will infringe Claim 6 of the '045 patent reexamination certificate pursuant to 35 U.S.C. § 271(g).

F. A permanent injunction, pursuant to 35 U.S.C. § 283, 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 Claims 6 and 12, 14-16 of the '045 patent reexamination certificate for the full term thereof;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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