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. _____
MICRO LABS LIMITED and MICRO LABS USA, 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 Micro Labs Limited, and Micro Labs USA, Inc. (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 Zymaxid® gatifloxacin ophthalmic solution, 0.5 w/v %, 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 Micro Labs Limited is an Indian corporation with a place of business at 27 Race Course Road, Bangalore 560 001, India.

6. On information and belief, defendant Micro Labs USA, Inc. is a corporation organized under the laws of the state of New Jersey, with a place of business at 104 Carnegie Center, Suite 216, Princeton, NJ 08549. Upon information and belief, Micro Labs USA Inc. is a wholly owned subsidiary of Micro Labs Limited.

7. On information and belief, Defendants import, distribute, manufacture, market, offer for sale and/or sell generic pharmaceutical products throughout the United States, including the State of Delaware.

8. On information and belief, Micro Labs USA, Inc. is the U.S. agent for Micro Labs Limited for at least its ANDA filings with the Food and Drug Administration.

9. Micro Labs Limited's website states "Micro Labs USA Inc., as the agent for Micro Labs Limited using the expertise of R&D centers in Bangalore and Mumbai is planning to file fifteen ANDA's in FY 2014." Exhibit B.

10. On information and belief, defendant Micro Labs USA, Inc. imports, distributes, markets, offers for sale and/or sells numerous generic drugs manufactured and supplied by Micro Labs Limited throughout the United States, including the State of Delaware.

11. Micro Labs Limited's website states that Micro Labs USA "will be marketing high quality, generic medications that will be trusted by patients and health care

professionals. These products will be manufactured in state of the art FDA approved facilities in Goa and Bangalore." Exhibit B, http://www.microlabsltd.com/business/international. Upon information and belief, the FDA approved facilities in Goa and Bangalore are owned and operated by Micro Labs Limited. See, Exhibit C obtained from http://www.microlabsltd.com/frontpages/corppresentation at 8-10 and 13-14. Upon information and belief, Defendants' proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 will be manufactured at a Bangalore, India plant owned by Micro Labs Limited. *Id.* at 9.

12. On information and belief, Micro Labs Limited, directly or indirectly through its U.S. agent, Micro Labs USA, Inc., submitted ANDA No. 206-446 to the United States Food and Drug Administration, seeking approval to commercially manufacture, use or sell, in the United States, Defendants' proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 prior to the expiration of the '045 patent.

13. On information and belief, Defendants are formulating and/or planning to formulate their proposed gatifloxacin ophthalmic solution, 0.5 w/v %, which is the subject of ANDA No. 206-446, 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 proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of Defendants' ANDA.

14. 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.

15. Upon information and belief, Defendants collaborated, are collaborating, and/or will collaborate in the development, marketing, sale, and obtaining regulatory approval of generic copies of branded pharmaceutical products, including gatifloxacin ophthalmic solution, 0.5 w/v %.

Jurisdiction and Venue

16. Paragraphs 1-15 are incorporated herein as set forth above.

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

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

19. This Court has personal jurisdiction over Defendants because of their substantial and continuing contacts with Delaware. On information and belief, Defendants directly or indirectly, and in concert with one another, purposefully offer to sell, sell, market, distribute, and/or manufacture goods, including generic pharmaceutical products, for sale in the United States, including 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, *e.g*, in *Alcon Res. Ltd. v. Micro Labs Limited and Micro Labs USA Inc.*, 14-cv-14 (D. Del.).

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

Background

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

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

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

24. 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.

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

26. The August 9, 2013, district court decision is presently on appeal before the Court of Appeals for the Federal Circuit. Oral argument took place on May 7, 2014, and a decision is expected later this year.

27. 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.

28. 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

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

30. 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.

31. On information and belief, Defendants filed ANDA No. 206-446, with a Paragraph IV certification, for approval to commercially market their proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446.

32. Upon information and belief, ANDA No. 206-446 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 gatifloxacin ophthalmic solution, 0.5 w/v %, to Allergan's Zymaxid® which is the subject of NDA No. 22-548.

33. In a letter dated July 17, 2014, Defendants provided notice to Plaintiffs that they had submitted to the FDA ANDA No. 206-446 for approval to commercially market a generic copy of the gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of Allergan's NDA No. 22-548. Allergan received that letter on July 18, 2014. Senju and Kyorin received the letter thereafter.

34. The July 17, 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. 206-446 was filed with a Paragraph IV certification to obtain approval to market Defendants' proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 before the expiration of the '045 patent.

35. Defendants were necessarily aware of the patent-in-suit when they filed ANDA No. 206-446 containing the Paragraph IV certification with the FDA.

36. Plaintiffs are commencing this action within forty-five days of the date they received Defendants' July 17, 2014, Paragraph IV notice letter of ANDA No. 206-446 containing the Paragraph IV certification.

COUNT 1

Direct Infringement of Claims 6, 12, and 14-16 of the '045 patent by ANDA No. 206-446

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

38. Defendants' submission of ANDA No. 206-446 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of their proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446, in the United States before the expiration of the '045 patent is an act of infringement of Claims 6, 12, and 14-16 of the '045 patent reexamination certificate under 35 U.S.C. § 271(e)(2)(A).

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

40. Defendants' participation in the submission of ANDA No. 206-446 and their §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

41. On information and belief, Defendants will financially benefit from the submission and, if received, approval of ANDA No. 206-446.

42. Upon information and belief, Defendants were aware of the existence of the '045 patent and were aware that the filing of ANDA No. 206-446 and a Paragraph IV certification with respect to the '045 patent constituted infringement of the '045 patent reexamination certificate.

COUNT 2

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

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

44. 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).

45. 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.

46. 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 proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 prior to the expiration of the '045 patent.

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

48. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of the proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 prior to the expiration of the '045 patent will infringe Claims 6, 12 and 14-16 of the '045 patent reexamination certificate.

49. Plaintiffs are entitled to a declaration that, if Defendants, prior to patent expiry, commercially import, manufacture, use, offer for sale, or sell the proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 within in the United States or import it into the United States, they will infringe Claims 6, 12, and 14-16 of the '045 patent reexamination certificate.

50. 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

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

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

53. 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.

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

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

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

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

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

59. Plaintiffs are entitled to a declaration that Defendants' submission of ANDA No. 206-446 to the FDA for the gatifloxacin ophthalmic solution, 0.5 w/v %, claimed in the '045 patent certificate, with the purpose of obtaining approval to engage in the commercial manufacture abroad and importation, use or sale of Defendants' proposed gatifloxacin ophthalmic solution, 0.5 w/v %, in United States prior to the expiration of the '045 patent, infringes Claim 6 set forth in the '045 patent reexamination certificate pursuant to 35 U.S.C. § 271(g).

60. 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 and 14-16 of the '045 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 206-446 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 Defendants' proposed gatifloxacin ophthalmic solution, 0.5 w/v % that is the subject of ANDA No. 206-446, prior to the expiry of the '045 patent, will infringe Claims 6, 12, and 14-16 of the '045 patent reexamination certificate;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206-446 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, 12, and 14-16 of the '045 patent reexamination certificate 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 proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 prior to the expiration of the '045 patent will infringe Claims 6, 12 and 14-16 of the '045 patent reexamination certificate pursuant to 35 U.S.C. § 271(a), (b) and/or (c).

E. A declaration that Defendants' commercial manufacture, sale, offer to sell, use in the United Sates, or importation into the United States, of the proposed gatifloxacin ophthalmic solution, 0.5 w/v %, that is the subject of ANDA No. 206-446 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, 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, 12 and 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.

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