IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALCON RESEARCH, LTD.,
ALCON LABORATORIES, INC.,
ALCON PHARMACEUTICALS, LTD., and
KYOWA HAKKO KIRIN CO., LTD.,

Plaintiffs,

v.

BARR LABORATORIES, INC.,

Defendants.

1:09-cv-0026SEB-DML
Civil Action No. _____

COMPLAINT

Plaintiffs Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Pharmaceuticals, Ltd., and Kyowa Hakko Kirin Co., Ltd. (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Barr Laboratories, Inc. ("Barr") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pataday® ophthalmic solution, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent Nos. 5,641,805, 6,995,186, and 7,402,609.

PARTIES

2. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

3. Plaintiff Alcon Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Plaintiff Alcon Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Route des Arsenaux 41, 1701 Fribourg, Switzerland.

5. Plaintiff Kyowa Hakko Kirin Co., Ltd. is a corporation organized and existing under the laws of Japan, having its principal place of business at 1-6-1 Ohtemachi, Chiyoda-ku, Tokyo 100-8185, Japan.

6. Upon information and belief, defendant Barr is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 225 Summit Avenue, Montvale, New Jersey 07645.

JURISDICTION AND VENUE

7. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, and 1400(b). Barr is subject to personal jurisdiction in Indiana because, among other things, upon information and belief, Barr is in the business of marketing pharmaceutical products, which it distributes and sells throughout the United States, including the State of Indiana and the Southern District of Indiana.

BACKGROUND

8. Pataday® is an ophthalmic solution for topical administration to the eye. The active ingredient of Pataday® is olopatadine hydrochloride.

COUNT I – U.S. PATENT NO. 5,641,805

9. Plaintiffs incorporate each of the preceding paragraphs 1-8 as if fully set

forth herein.

10. United States Patent No. 5,641,805 ("the '805 patent"), entitled "Topical Ophthalmic Formulations for Treating Allergic Eye Diseases" (Exhibit A hereto), was duly and legally issued on June 24, 1997, to Alcon Laboratories, Inc. and Kyowa Hakko Kogyo Co., Ltd., as assignees of John Michael Yanni, Stella M. Robertson, Eiji Hayakawa, and Masashi Nakakura.

11. Alcon Laboratories, Inc.'s interest in the '805 patent has been subsequently assigned to Alcon Research, Ltd.

12. Alcon Laboratories, Inc. sells drug products covered by the '805 patent under the trademark Pataday® pursuant to a New Drug Application held by Alcon Laboratories, Inc. and approved by the FDA.

13. Kyowa Hakko Kogyo, Co., Ltd.'s interest in the '805 patent has been subsequently assigned to Kyowa Hakko Kirin Co., Ltd.

14. Plaintiffs will be substantially and irreparably damaged by infringement of the '805 patent.

15. The use of Pataday® is covered by one or more claims of the '805 patent, and the '805 patent has been listed in connection with that drug product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

16. By letter dated November 24, 2008 (the "Notice Letter"), Barr notified Alcon, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that Barr had submitted to the FDA an ANDA, No. 90-848, for Barr's ophthalmic solution containing olopatadine hydrochloride, a drug product that is a generic version of Pataday® ("Barr's ANDA Product"). The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic

Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product prior to the expiration of the '805 patent.

17. In the Notice Letter, Barr also notified Alcon, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Barr had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to, *inter alia*, the '805 patent. Upon information and belief, Barr submitted ANDA No. 90-848 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '805 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Barr's ANDA Product.

18. The use of Barr's ANDA Product is covered by one or more claims of the '805 patent.

19. Barr has knowledge of the '805 patent.

20. Barr's filing of ANDA No. 90-848 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product before the expiration of the '805 patent is an act of infringement of the '805 patent.

21. The use of Barr's ANDA Product would infringe one or more claims of the '805 patent.

22. Upon information and belief, the use of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '805 patent.

23. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product with its

proposed labeling immediately and imminently upon approval of ANDA No. 90-848.

24. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '805 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

25. Upon information and belief, Barr knows that Barr's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '805 patent, and that Barr's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Barr plans and intends to, and will, contribute to infringement of the '805 patent immediately and imminently upon approval of ANDA No. 90-848.

26. The foregoing actions by Barr constitute and/or will constitute infringement of the '805 patent, active inducement of infringement of the '805 patent, and contribution to the infringement by others of the '805 patent.

27. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '805 patent, actively inducing infringement of the '805 patent, and contributing to the infringement by others of the '805 patent.

28. Unless Barr is enjoined from infringing the '805 patent, actively inducing infringement of the '805 patent, and contributing to the infringement by others of the '805 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – U.S. PATENT NO. 6,995,186

29. Plaintiffs incorporate each of the preceding paragraphs 1-28 as if fully set forth herein.

30. United States Patent No. 6,995,186 ("the '186 patent"), entitled

"Olopatadine Formulations for Topical Administration" (Exhibit B hereto), was duly and legally issued on February 7, 2006, to Alcon, Inc., as assignee of Ernesto J. Castillo, Wesley Wehsin Han, Huixiang Zhang, Haresh G. Bhagat, Onkar N. Singh, Joseph Paul Bullock, and Suresh C. Dixit.

31. The '186 patent has been subsequently assigned to Alcon Pharmaceuticals, Ltd.

32. Alcon Research, Ltd. is the exclusive licensee of the '186 patent.

33. Alcon Laboratories, Inc. sells drug products covered by the '186 patent under the trademark Pataday® pursuant to a New Drug Application held by Alcon Laboratories, Inc. and approved by the FDA.

34. Plaintiffs will be substantially and irreparably damaged by infringement of the '186 patent.

35. Pataday® and the use of Pataday® are covered by one or more claims of the '186 patent, and the '186 patent has been listed in connection with that drug product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

36. In its Notice Letter, Barr notified Alcon, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that Barr had submitted to the FDA an ANDA, No. 90-848, for Barr's ANDA Product. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product prior to the expiration of the '186 patent.

37. In the Notice Letter, Barr also notified Alcon, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Barr had filed certifications of the

type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to, *inter alia*, the '186 patent. Upon information and belief, Barr submitted ANDA No. 90-848 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '186 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product.

38. Barr's ANDA Product and the use of Barr's ANDA Product are covered by one or more claims of the '186 patent.

39. Barr has knowledge of the '186 patent.

40. Barr's filing of ANDA No. 90-848 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product before the expiration of the '186 patent is an act of infringement of the '186 patent.

41. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product would infringe one or more claims of the '186 patent.

42. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '186 patent.

43. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-848.

44. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '186 patent when its ANDA is approved, and plans and intends to,

and will, do so immediately and imminently upon approval.

45. Upon information and belief, Barr knows that Barr's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '186 patent, and that Barr's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Barr plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 90-848.

46. The foregoing actions by Barr constitute and/or will constitute infringement of the '186 patent, active inducement of infringement of the '186 patent, and contribution to the infringement by others of the '186 patent.

47. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '186 patent, actively inducing infringement of the '186 patent, and contributing to the infringement by others of the '186 patent.

48. Unless Barr is enjoined from infringing the '186 patent, actively inducing infringement of the '805 patent, and contributing to the infringement by others of the '186 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – U.S. PATENT NO. 7,402,609

49. Plaintiffs incorporate each of the preceding paragraphs 1-48 as if fully set forth herein.

50. United States Patent No. 7,402,609 ("the '609 patent"), entitled "Olopatadine Formulations for Topical Administration" (Exhibit C hereto), was duly and legally issued on July 22, 2008, to Alcon, Inc., as assignee of Ernesto J. Castillo, Wesley Wehsin Han, Huixiang Zhang, Haresh G. Bhagat, Onkar N. Singh, Joseph Paul Bullock, and Suresh C. Dixit.

51. The '609 patent has been subsequently assigned to Alcon Pharmaceuticals, Ltd.

52. Alcon Research, Ltd. is the exclusive licensee of the '609 patent.

53. Alcon Laboratories, Inc. sells drug products covered by the '609 patent under the trademark Pataday® pursuant to a New Drug Application held by Alcon Laboratories, Inc. and approved by the FDA.

54. Plaintiffs will be substantially and irreparably damaged by infringement of the '609 patent.

55. Pataday® is covered by one or more claims of the '609 patent, and the '609 patent has been listed in connection with that drug product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

56. In its Notice Letter, Barr notified Alcon, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that Barr had submitted to the FDA an ANDA, No. 90-848, for Barr's ANDA Product. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product prior to the expiration of the '609 patent.

57. In the Notice Letter, Barr also notified Alcon, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Barr had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to, *inter alia*, the '609 patent. Upon information and belief, Barr submitted ANDA No. 90-848 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '609 patent is invalid, unenforceable, and/or will not be infringed by the

manufacture, use, offer for sale, sale, or importation of Barr's ANDA Product.

58. Barr's ANDA Product is covered by the claim of the '609 patent.

59. Barr has knowledge of the '609 patent.

60. Barr's filing of ANDA No. 90-848 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product before the expiration of the '609 patent is an act of infringement of the '609 patent.

61. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product would infringe the claim of the '609 patent.

62. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '609 patent.

63. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-848.

64. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '609 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

65. Upon information and belief, Barr knows that Barr's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '609 patent, and that Barr's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Barr plans and intends to, and will, contribute

to infringement of the '609 patent immediately and imminently upon approval of ANDA No. 90-848.

66. The foregoing actions by Barr constitute and/or will constitute infringement of the '609 patent, active inducement of infringement of the '609 patent, and contribution to the infringement by others of the '609 patent.

67. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '609 patent, actively inducing infringement of the '609 patent, and contributing to the infringement by others of the '609 patent.

68. Unless Barr is enjoined from infringing the '609 patent, actively inducing infringement of the '805 patent, and contributing to the infringement by others of the '609 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Barr has infringed the '805, '186, and '609 patents;

(b) A judgment ordering that the effective date of any FDA approval for Barr to make, use, offer for sale, sell, market, distribute, or import Barr's ANDA Product, or any product that infringes the '805, '186, and '609 patents, be not earlier than the latest of the expiration dates of the '805, '186, and '609 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Barr, and all persons acting in concert with Barr, from making, using, selling, offering for sale, marketing, distributing, or importing Barr's ANDA Product, or any product that infringes the '805, '186, and '609 patents, or the inducement of or the contribution to any of the foregoing, prior to the expiration dates of the '805, '186, and '609 patents, inclusive of any extension(s) and additional

period(s) of exclusivity;

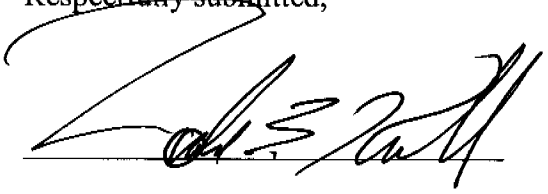
(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Barr's ANDA Product, or any product that infringes the '805, '186, and '609 patents, prior to the expiration date of the '805, '186, and '609 patents, will infringe, actively induce infringement of, and contribute to the infringement by others of the '805, '186, and '609 patents;

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

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,



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