UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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

Plaintiffs,

v.

APOTEX INC. and
APOTEX CORP.

Defendants.

1:09-cv-0102SEB-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 defendants Apotex Inc. and Apotex Corp. 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 Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Dr., Weston, Ontario M9L 1T9, Canada.

7. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

8. Except where otherwise noted, Apotex Inc. and Apotex Corp. are referred to collectively herein as "Apotex."

JURISDICTION AND VENUE

9. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, and 1400(b).

10. Upon information and belief, Apotex Inc. ships Apotex products from Canada to a distribution and operations center located in Indianapolis, Indiana.

11. Upon information and belief, Apotex Corp., a wholly-owned subsidiary of Apotex Inc., operates the operations and distribution center in Indianapolis through which it distributes Apotex products for sale throughout the United States.

BACKGROUND

12. 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

13. Plaintiffs incorporate each of the preceding paragraphs 1-12 as if fully set forth herein.

14. 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.

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

16. 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.

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

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

19. 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*.

20. By letter dated January 7, 2009 (the "Notice Letter"), Apotex notified Alcon, Inc., Alcon Research, Ltd., Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.) , and Kyowa Hakko Kirin Co., Ltd. that Apotex had submitted to the FDA an ANDA, No. 90-918, for Apotex's ophthalmic solution containing olopatadine hydrochloride, a drug product that is a generic version of Pataday® ("Apotex'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 Apotex's ANDA Product prior to the expiration of the '805 patent.

21. In the Notice Letter, Apotex also notified Alcon, Inc., Alcon Research, Ltd., Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.), and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Apotex 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, Apotex submitted ANDA No. 90-918 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 Apotex's ANDA Product.

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

23. Apotex has knowledge of the '805 patent.

24. Apotex's filing of ANDA No. 90-918 for the purpose of obtaining

approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '805 patent is an act of infringement of the '805 patent.

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

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

27. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-918.

28. Upon information and belief, Apotex 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.

29. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '805 patent, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '805 patent immediately and imminently upon approval of ANDA No. 90-918.

30. The foregoing actions by Apotex 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.

31. Upon information and belief, Apotex 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.

32. Unless Apotex 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

33. Plaintiffs incorporate each of the preceding paragraphs 1-32 as if fully set forth herein.

34. 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.

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

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

37. 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.

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

39. 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*.

40. In its Notice Letter, Apotex notified Alcon, Inc., Alcon Research, Ltd., Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.), and Kyowa Hakko Kirin Co., Ltd. that Apotex had submitted to the FDA an ANDA, No. 90-918, for Apotex'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 Apotex's ANDA Product prior to the expiration of the '186 patent.

41. In the Notice Letter, Apotex also notified Alcon, Inc., Alcon Research, Ltd., Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.), and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Apotex 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, Apotex submitted ANDA No. 90-918 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 Apotex's ANDA Product.

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

43. Apotex has knowledge of the '186 patent.

44. Apotex's filing of ANDA No. 90-918 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '186 patent is an act of infringement of the '186 patent.

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

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

47. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-918.

48. Upon information and belief, Apotex 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.

49. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '186 patent, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 90-918.

50. The foregoing actions by Apotex 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.

51. Upon information and belief, Apotex 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.

52. Unless Apotex 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

53. Plaintiffs incorporate each of the preceding paragraphs 1-52 as if fully set forth herein.

54. 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.

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

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

57. 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.

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

59. Pataday® is covered by the claim 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*.

60. In its Notice Letter, Apotex notified Alcon, Inc., Alcon Research, Ltd.,

Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.), and Kyowa Hakko Kirin Co., Ltd. that Apotex had submitted to the FDA an ANDA, No. 90-918, for Apotex'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 Apotex's ANDA Product prior to the expiration of the '609 patent.

61. In the Notice Letter, Apotex also notified Alcon, Inc., Alcon Research, Ltd., Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.), and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Apotex 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, Apotex submitted ANDA No. 90-918 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 Apotex's ANDA Product.

62. Apotex's ANDA Product is covered by the claim of the '609 patent.

63. Apotex has knowledge of the '609 patent.

64. Apotex's filing of ANDA No. 90-918 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '609 patent is an act of infringement of the '609 patent.

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

66. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product in accordance with and

as directed by Apotex's proposed labeling for that product would infringe the claim of the '609 patent.

67. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-918.

68. Upon information and belief, Apotex 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.

69. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '609 patent, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '609 patent immediately and imminently upon approval of ANDA No. 90-918.

70. The foregoing actions by Apotex 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.

71. Upon information and belief, Apotex 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.

72. Unless Apotex 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 Apotex has infringed the '805, '186, and '609 patents;

(b) A judgment ordering that the effective date of any FDA approval for Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex'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 Apotex, and all persons acting in concert with Apotex, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex'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 Apotex's ANDA Product, or any product that infringes the '805, '186, and '609 patents, prior to the expiration dates 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;

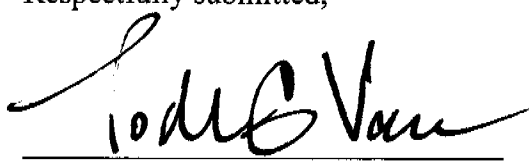
(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(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.

Dated: February 2, 2009

Respectfully submitted,



Donald E. Knebel (5264-49)
dknebel@btlaw.com
Todd G. Vare (18458-59)
todd.vare@btlaw.com
Deborah Pollack-Milgate (22475-49)
dmilgate@btlaw.com
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204
(317) 236-1313
(317) 231-7433 (Facsimile)

Of Counsel
Bruce R. Genderson
bgenderson@wc.com
Adam L. Perlman
aperlman@wc.com
Thomas H. Selby
tselby@wc.com
Daniel P. Shanahan
dshanahan@wc.com
Shelley Webb
swebb@wc.com
Kendra P. Robins
krobins@wc.com
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000
(202) 434-5029 (Facsimile)

Attorneys for Plaintiffs Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Pharmaceuticals, Ltd., and Kyowa Hakko Kirin Co., Ltd.