

**FILED**

JAN 27 2010

U.S. DISTRICT COURT  
INDIANAPOLIS, INDIANA

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. )

Civil Action No. \_\_\_\_\_

SANDOZ INC., )  
Defendant. )

**1:10-cv-0106 LJM-DML**

**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 Sandoz Inc. 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 Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

#### **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). Sandoz is subject to personal jurisdiction in Indiana because, among other things, upon information and belief, Sandoz 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 December 14, 2009 (the “Notice Letter”), Sandoz notified Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Inc., and Kyowa Hakko Kirin Co., Ltd., that Sandoz had submitted to the FDA an ANDA, No. 200410, for Sandoz’s Olopatadine Hydrochloride ophthalmic solution/drops 0.2% Eq. Base (“Sandoz’s ANDA Product”). Sandoz’s ANDA Product is a drug product that is a generic version of Pataday™, and on

information and belief, Sandoz's ANDA Product contains the same ingredients, or equivalents thereof, in the same amounts, or equivalent amounts, as Pataday™. 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 Sandoz's ANDA Product prior to the expiration of the '805 patent.

17. In the Notice Letter, Sandoz also notified Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Inc., and Kyowa Hakko Kirin Co., Ltd., that, as part of its ANDA, Sandoz 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, Sandoz submitted ANDA No. 200410 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 Sandoz's ANDA Product.

18. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), for each claim of the '805 patent that Sandoz believes would not be infringed by the making, using, offering for sale, sale, or importation of Sandoz's ANDA Product, Sandoz was required to provide in its Notice Letter a full and detailed explanation of why each such claim is or would not be infringed.

19. Sandoz did not assert in its Notice Letter that the making, using, offering for sale, sale, or importation of Sandoz's ANDA Product would not infringe at least one claim of the '805 patent.

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

21. Sandoz has knowledge of the '805 patent.

22. Sandoz's filing of ANDA No. 200410 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '805 patent is an act of infringement of the '805 patent.

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

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

25. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 200410.

26. Upon information and belief, Sandoz 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.

27. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '805 patent, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '805 patent immediately and imminently upon approval of ANDA No. 200410.

28. The foregoing actions by Sandoz 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.

29. Upon information and belief, Sandoz 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.

30. Unless Sandoz 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**

31. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

32. 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.

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

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

35. 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.

36. Plaintiffs will be substantially and irreparably damaged by infringement of

the '186 patent.

37. 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*.

38. In its Notice Letter, Sandoz notified Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Inc., and Kyowa Hakko Kirin Co., Ltd., that Sandoz had submitted to the FDA an ANDA, No. 200410, for Sandoz's ANDA Product. Sandoz's ANDA Product is a drug product that is a generic version of Pataday™, and on information and belief, Sandoz's ANDA Product contains the same ingredients, or equivalents thereof, in the same amounts, or equivalent amounts, as Pataday™. 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 Sandoz's ANDA Product prior to the expiration of the '186 patent.

39. In the Notice Letter, Sandoz also notified Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Inc., and Kyowa Hakko Kirin Co., Ltd., that, as part of its ANDA, Sandoz 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, Sandoz submitted ANDA No. 200410 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 Sandoz's ANDA Product.

40. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), for each claim of the '186 patent that Sandoz believes would not be infringed by the making,

using, offering for sale, sale, or importation of Sandoz's ANDA Product, Sandoz was required to provide in its Notice Letter a full and detailed explanation of why each such claim is or would not be infringed.

41. Sandoz did not assert in its Notice Letter that the making, using, offering for sale, sale, or importation of Sandoz's ANDA Product would not infringe at least one claim of the '186 patent.

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

43. Sandoz has knowledge of the '186 patent.

44. Sandoz's filing of ANDA No. 200410 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz'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 Sandoz'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 Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '186 patent.

47. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 200410.

48. Upon information and belief, Sandoz 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, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '186 patent, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 200410.

50. The foregoing actions by Sandoz 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, Sandoz 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 Sandoz is enjoined from infringing the '186 patent, actively inducing infringement of the '186 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, Sandoz notified Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Inc., and Kyowa Hakko Kirin Co., Ltd., that Sandoz had submitted to the FDA an ANDA, No. 200410, for Sandoz's ANDA Product. Sandoz's ANDA Product is a drug product that is a generic version of Pataday™, and on information and belief, Sandoz's ANDA Product contains the same ingredients, or equivalents thereof, in the same amounts, or equivalent amounts, as Pataday™. 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 Sandoz's ANDA Product prior to the expiration of the '609 patent.

61. In the Notice Letter, Sandoz also notified Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon Inc., and Kyowa Hakko Kirin Co., Ltd., that, as part of its ANDA,

Sandoz 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, Sandoz submitted ANDA No. 200410 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 Sandoz's ANDA Product.

62. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), for each claim of the '609 patent that Sandoz believes would not be infringed by the making, using, offering for sale, sale, or importation of Sandoz's ANDA Product, Sandoz was required to provide in its Notice Letter a full and detailed explanation of why each such claim is or would not be infringed.

63. Sandoz did not assert in its Notice Letter that the making, using, offering for sale, sale, or importation of Sandoz's ANDA Product would not infringe the claim of the '609 patent.

64. Sandoz's ANDA Product is covered by the claim of the '609 patent.

65. Sandoz has knowledge of the '609 patent.

66. Sandoz's filing of ANDA No. 200410 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '609 patent is an act of infringement of the '609 patent.

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

68. Upon information and belief, the manufacture, use, offer for sale, sale,

marketing, distribution, and/or importation of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe the claim of the '609 patent.

69. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 200410.

70. Upon information and belief, Sandoz 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.

71. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '609 patent, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '609 patent immediately and imminently upon approval of ANDA No. 200410.

72. The foregoing actions by Sandoz 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.

73. Upon information and belief, Sandoz 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.

74. Unless Sandoz is enjoined from infringing the '609 patent, actively inducing infringement of the '609 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 Sandoz has infringed the '805, '186, and '609 patents;
- (b) A judgment ordering that the effective date of any FDA approval for Sandoz to make, use, offer for sale, sell, market, distribute, or import Sandoz'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 Sandoz, and all persons acting in concert with Sandoz, from making, using, selling, offering for sale, marketing, distributing, or importing Sandoz'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 Sandoz'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.

Respectfully submitted,

Dated: January 27, 2010



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