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

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

Plaintiffs,

v.

WATSON LABORATORIES, INC.,
WATSON PHARMACEUTICALS, INC.,
and WATSON PHARMA, INC.,

Defendants.

Civil Action No. 1:11-cv-0786 TWP DKL

COMPLAINT

Plaintiffs Alcon Research, Ltd. and Alcon Pharmaceuticals, Ltd., (collectively "Alcon"), and Kyowa Hakko Kirin Co., Ltd. ("Kyowa"), 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 Watson's filing 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 ("the '805 patent"), 6,995,186 ("the '186 patent"), and 7,402,609 ("the '609 patent").

PARTIES

2. Plaintiff Alcon Research, Ltd. is a corporation organized and existing

under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

3. 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.

4. 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.

5. Upon information and belief, defendant Watson Laboratories Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

6. Upon information and belief, defendant Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

7. Upon information and belief, defendant Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

8. Upon information and belief, Watson Laboratories and Watson Pharma are wholly owned subsidiaries of Watson Pharmaceuticals. Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma are collectively referred to herein as "Watson."

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), and 2201 and 2202.

10. Watson is subject to personal jurisdiction in Indiana and the Southern District of Indiana because, among other things, it 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. It regularly transacts and/or solicits business in the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court here.

11. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and/or Watson Pharma share common employees, officers and directors.

12. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson's Generic division.

13. Upon information and belief, Watson Pharmaceuticals organizes its operations by division, including at least Generic, Brand, and Distribution.

14. Upon information and belief, Watson's Generic division is responsible for developing and manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market, and relies on contributions from Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma.

15. Upon information and belief, Watson Laboratories submits ANDAs and manufactures generic copies of branded pharmaceutical products for the U.S. market.

16. Upon information and belief, Watson Pharma markets and sells Watson

drug products in the United States, including in the State of Indiana and the Southern District of Indiana.

17. Upon information and belief, Watson Pharma is a corporation registered with the Secretary of State to conduct business in the State of Indiana. Upon information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and/or Watson Laboratories, distributes and sells in Indiana, the Southern District of Indiana, and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, Watson Pharma and Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are at less than arm's length.

18. Upon information and belief, Watson Pharmaceuticals and/or Watson Laboratories earns revenue from the distribution in the State of Indiana and the Southern District of Indiana by Watson Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

19. Upon information and belief, Watson Pharmaceuticals and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission by Watson Laboratories to the U.S. Food and Drug Administration ("FDA") of ANDA No. 202526, the ANDA at issue in this litigation. For instance, by letter dated April 27, 2011, Watson Laboratories directed Plaintiffs to send any written notice regarding confidential access concerning ANDA No. 202526 to Mr. Brian Anderson, who is registered with the State Bar of California as an attorney employed by Watson Pharmaceuticals, Inc.

COUNT I - INFRINGEMENT OF THE '805 PATENT

20. Plaintiffs incorporate each of the preceding paragraphs 1-19 as if fully set forth herein.

21. 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.

22. The '805 patent claims, *inter alia*, a method of treating allergic eye disease in humans comprising stabilizing conjunctival mast cells by topically administering to the eye a composition comprising a therapeutically effective amount of olopatadine, or a pharmaceutically acceptable salt thereof.

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

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

25. Alcon and Kyowa will be substantially and irreparably damaged by infringement of the '805 patent.

26. 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*, commonly referred to as the "Orange Book."

27. By letter dated April 27, 2011 (the "Notice Letter"), Watson notified Plaintiffs that Watson had submitted to the FDA an ANDA, No. 202526, for Watson's

ophthalmic solution containing olopatadine hydrochloride, a drug product that is a generic version of PATADAY™ ("Watson'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 Watson's ANDA Product prior to the expiration of, *inter alia*, the '805 patent.

28. In the Notice Letter, Watson also notified Plaintiffs that, as part of its ANDA, Watson 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, Watson submitted ANDA No. 202526 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, and/or importation of Watson's ANDA Product.

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

30. Watson has knowledge of the '805 patent.

31. Watson's submission of ANDA No. 202526 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Product before the expiration of the '805 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 202526.

33. The use of Watson's ANDA Product would infringe one or more claims of

the '805 patent.

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

35. Upon information and belief, Watson 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.

36. Upon information and belief, Watson knows that Watson's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '805 patent, and that Watson's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '805 patent immediately and imminently upon approval of ANDA No. 202526.

37. Notwithstanding Watson's knowledge of the claims of the '805 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 202526 prior to the expiration of the '805 patent.

38. The foregoing actions by Watson 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.

39. Upon information and belief, Watson has acted with full knowledge of the '805 patent and without a reasonable basis for believing that it would not be liable for infringement of the '805 patent, active inducement of infringement of the '805 patent, and/or

contribution to the infringement by others of the '805 patent.

40. Unless Watson 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 - INFRINGEMENT OF THE '186 PATENT

41. Plaintiffs incorporate each of the preceding paragraphs 1-40 as if fully set forth herein.

42. 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.

43. The '186 patent claims, *inter alia*, a topically administrable solution composition for treating allergic or inflammatory disorders of the eye and nose comprising olopatadine and a polymeric ingredient, where the amount of olopatadine is 0.17-62% (w/v), the polymeric ingredient is a polymeric physical stability-enhancing ingredient consisting essentially of polyvinylpyrrolidone or polystyrene sulfonic acid in an amount sufficient to enhance the physical stability of the solution, and wherein the composition has a viscosity of 1-2 cps, and does not contain polyvinyl alcohol, polyvinyl acrylic acid, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose or xanthan gum.

44. The '186 patent also claims, *inter alia*, a method of treating allergic or inflammatory conditions of the eye comprising topically administering to the eye a solution composition comprising olopatadine and a polymeric ingredient, the improvement wherein the solution is administered once per day, the amount of olopatadine in the solution 0.17-0.25%

(w/v) and the polymeric ingredient is a polymeric physical stability-enhancing ingredient consisting essentially of polyvinylpyrrolidone or polystyrene sulfonic acid in an amount sufficient to enhance the physical stability of the solution, and wherein the composition has a viscosity of 1-2 cps, and does not contain polyvinyl alcohol, polyvinyl acrylic acid, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose or xanthan gum.

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

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

47. Alcon will be substantially and irreparably damaged by infringement of the '186 patent.

48. 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 Orange Book.

49. In the Notice Letter, Watson notified Plaintiffs that Watson had submitted to the FDA ANDA No. 202526 for Watson's ANDA Product. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Product prior to the expiration of, *inter alia*, the '186 patent.

50. In the Notice Letter, Watson also notified Plaintiffs that, as part of its ANDA, Watson 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, Watson submitted ANDA No. 202526 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 Watson's ANDA Product.

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

52. Watson has knowledge of the '186 patent.

53. Watson's submission of ANDA No. 202526 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's ANDA Product before the expiration of the '186 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 202526.

55. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe one or more claims of the '186 patent.

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

57. Upon information and belief, Watson 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.

58. Upon information and belief, Watson knows that Watson's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '186 patent, and that Watson's ANDA Product and its proposed labeling are not suitable for

substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 202526.

59. Notwithstanding Watson's knowledge of the claims of the '186 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 202526 prior to the expiration of the '186 patent.

60. The foregoing actions by Watson 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.

61. Upon information and belief, Watson has acted with full knowledge of the '186 patent and without a reasonable basis for believing that it would not be liable for infringement of the '186 patent, active inducement of infringement of the '186 patent, and/or contribution to the infringement by others of the '186 patent.

62. Unless Watson 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, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT III - INFRINGEMENT OF THE '609 PATENT

63. Plaintiffs incorporate each of the preceding paragraphs 1-62 as if fully set forth herein.

64. 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.

65. The '609 patent claims a topically administrable solution composition for treating allergic or inflammatory disorders of the eye and nose, wherein the solution has a pH from 6.5-7.5 and a viscosity of 1-2 cps, and wherein the solution consists essentially of 0.18-0.22% (w/v) olopatadine; 1.5-2% (w/v) polyvinylpyrrolidone having a weight average molecular weight of 50,000-60,000; a preservative selected from the group consisting of benzalkonium chloride; benzododecinum bromide; and polyquaternium-l; edetate disodium; a tonicity-adjusting agent selected from the group consisting of mannitol and sodium chloride; a buffering agent selected from the group consisting of phosphates and borates; optionally a pH-adjusting agent selected from the group consisting of NaOH and HCl; and water.

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

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

68. Alcon will be substantially and irreparably damaged by infringement of the '609 patent.

69. 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 Orange Book.

70. In the Notice Letter, Watson notified Plaintiffs that Watson had submitted to the FDA ANDA No. 202526 for Watson's ANDA Product. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Product prior to the expiration of, *inter alia*, the '609 patent.

71. In the Notice Letter, Watson also notified Plaintiffs that, as part of its

ANDA, Watson 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, Watson submitted ANDA No. 202526 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, and/or importation of Watson's ANDA Product.

72. Watson's ANDA Product is covered by the claim of the '609 patent.

73. Watson has knowledge of the '609 patent.

74. Watson's submission of ANDA No. 202526 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's ANDA Product before the expiration of the '609 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

75. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 202526.

76. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe the claim of the '609 patent.

77. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product in accordance with and as directed by Watson's proposed product labeling would infringe the claim of the '609 patent.

78. Upon information and belief, Watson 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.

79. Notwithstanding Watson's knowledge of the claims of the '609 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 202526 prior to the expiration of the '609 patent.

80. The foregoing actions by Watson constitute and/or will constitute infringement and active inducement of infringement of the '609 patent.

81. Upon information and belief, Watson has acted with full knowledge of the '609 patent and without a reasonable basis for believing that it would not be liable for infringement and active inducement of infringement of the '609 patent.

82. Unless Watson is enjoined from infringing and actively inducing infringement of the '609 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '805 PATENT

83. Plaintiffs incorporate each of the preceding paragraphs 1-82 as if fully set forth herein.

84. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon and Kyowa on the one hand and Watson on the other regarding Watson's infringement, active inducement of infringement, and contribution to the infringement by others of the '805 patent.

85. The '805 patent claims, *inter alia*, a method of treating allergic eye disease in humans comprising stabilizing conjunctival mast cells by topically administering to the eye a composition comprising a therapeutically effective amount of olopatadine, or a pharmaceutically acceptable salt thereof.

86. In the Notice Letter described in paragraph 27 above, Watson notified Plaintiffs that Watson had submitted ANDA No. 202526 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of Watson's ANDA Product prior to the expiration of, *inter alia*, the '805 patent.

87. In the Notice Letter, Watson also notified Plaintiffs that, as part of its ANDA, Watson 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).

88. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 202526.

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

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

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

92. Upon information and belief, Watson 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.

93. Upon information and belief, Watson knows that Watson's ANDA Product and its product labeling are especially made or adapted for use in infringing the '805 patent, that Watson's ANDA Product is not a staple article or commodity of commerce, and that

Watson's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '805 patent immediately and imminently upon approval of ANDA No. 202526.

94. Notwithstanding Watson's knowledge of the claims of the '805 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 202526 prior to the expiration of the '805 patent.

95. The foregoing actions by Watson will constitute active inducement of infringement of, and contribute to the infringement by others of, the '805 patent.

96. Upon information and belief, Watson has acted with full knowledge of the '805 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '805 patent and contribution to the infringement by others of the '805 patent.

97. Unless Watson is enjoined from infringing, inducing infringement of, and contributing to the infringement by others of, the '805 patent, Alcon and Kyowa will suffer irreparable injury. Alcon and Kyowa have no adequate remedy at law.

98. The Court should declare that the use of Watson's ANDA Product, or any other drug product whose use is covered by United States Patent No. 5,641,805, will infringe that patent, and that the commercial manufacture, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product whose use is covered by United States Patent No. 5,641,805, will induce infringement of, and contribute to the infringement by others of, that patent.

COUNT V - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '186 PATENT

99. Plaintiffs incorporate each of the preceding paragraphs 1-98 as if fully set forth herein.

100. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Watson on the other regarding Watson's infringement, active inducement of infringement, and contribution to the infringement by others of the '186 patent.

101. The '186 patent claims, *inter alia*, a topically administrable solution composition for treating allergic or inflammatory disorders of the eye and nose comprising olopatadine and a polymeric ingredient, where the amount of olopatadine is 0.17-62% (w/v), the polymeric ingredient is a polymeric physical stability-enhancing ingredient consisting essentially of polyvinylpyrrolidone or polystyrene sulfonic acid in an amount sufficient to enhance the physical stability of the solution, and wherein the composition has a viscosity of 1-2 cps, and does not contain polyvinyl alcohol, polyvinyl acrylic acid, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose or xanthan gum.

102. The '186 patent also claims, *inter alia*, a method of treating allergic or inflammatory conditions of the eye comprising topically administering to the eye a solution composition comprising olopatadine and a polymeric ingredient, the improvement wherein the solution is administered once per day, the amount of olopatadine in the solution 0.17-0.25% (w/v) and the polymeric ingredient is a polymeric physical stability-enhancing ingredient consisting essentially of polyvinylpyrrolidone or polystyrene sulfonic acid in an amount sufficient to enhance the physical stability of the solution, and wherein the composition has a viscosity of 1-2 cps, and does not contain polyvinyl alcohol, polyvinyl acrylic acid,

hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose or xanthan gum.

103. In the Notice Letter described in paragraph 27 above, Watson notified Plaintiffs that Watson had submitted ANDA No. 202526 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of Watson's ANDA Product prior to the expiration of, *inter alia*, the '186 patent.

104. In the Notice Letter, Watson also notified Plaintiffs that, as part of its ANDA, Watson 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).

105. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 202526.

106. Watson's ANDA Product and the use of Watson's ANDA Product is covered by one or more claims of the '186 patent.

107. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe one or more claims of the '186 patent.

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

109. Upon information and belief, Watson 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.

110. Upon information and belief, Watson knows that Watson's ANDA Product and its product labeling are especially made or adapted for use in infringing the '186

patent, that Watson's ANDA Product is not a staple article or commodity of commerce, and that Watson's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 202526.

111. Notwithstanding Watson's knowledge of the claims of the '186 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 202526 prior to the expiration of the '186 patent.

112. The foregoing actions by Watson will constitute infringement of, active inducement of infringement of, and contribute to the infringement by others of the '186 patent.

113. Upon information and belief, Watson has acted with full knowledge of the '186 patent and without a reasonable basis for believing that it would not be liable for infringement of the '186 patent, active inducement of infringement of the '186 patent, and contribution to the infringement by others of the '186 patent.

114. Unless defendant Watson is enjoined from infringing, inducing infringement of, and contributing to the infringement by others of, the '186 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

115. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 6,995,186, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent.

COUNT VI - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '609 PATENT

116. Plaintiffs incorporate each of the preceding paragraphs 1-115 as if fully set forth herein.

117. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Watson on the other regarding Watson's infringement and active inducement of infringement of the '609 patent.

118. The '609 patent claims a topically administrable solution composition for treating allergic or inflammatory disorders of the eye and nose, wherein the solution has a pH from 6.5-7.5 and a viscosity of 1-2 cps, and wherein the solution consists essentially of 0.18-0.22% (w/v) olopatadine; 1.5-2% (w/v) polyvinylpyrrolidone having a weight average molecular weight of 50,000-60,000; a preservative selected from the group consisting of benzalkonium chloride; benzododecinum bromide; and polyquaternium-l; edetate disodium; a tonicity-adjusting agent selected from the group consisting of mannitol and sodium chloride; a buffering agent selected from the group consisting of phosphates and borates; optionally a pH-adjusting agent selected from the group consisting of NaOH and HCl; and water.

119. In the Notice Letter described in paragraph 27 above, Watson notified Plaintiffs that Watson had submitted ANDA No. 202526 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of Watson's ANDA Product prior to the expiration of, *inter alia*, the '609 patent.

120. In the Notice Letter, Watson also notified Plaintiffs that, as part of its ANDA, Watson 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).

121. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 202526.

122. Watson's ANDA Product is covered by the claim of the '609 patent.

123. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe the claim of the '609 patent.

124. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product in accordance with and as directed by Watson's proposed product labeling would infringe the claim of the '609 patent.

125. Upon information and belief, Watson 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.

126. Notwithstanding Watson's knowledge of the claim of the '609 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 202526 prior to the expiration of the '609 patent.

127. The foregoing actions by Watson will constitute infringement and active inducement of infringement of the '609 patent.

128. Upon information and belief, Watson has acted with full knowledge of the '609 patent and without a reasonable basis for believing that it would not be liable for infringement and active inducement of infringement of the '609 patent.

129. Unless defendant Watson is enjoined from infringing and inducing infringement of the '609 patent, Alcon will suffer irreparable injury. Alcon has no adequate

remedy at law.

130. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 7,402,609, will infringe and will induce the infringement of that patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that United States Patent Nos. 5,641,805; 6,995,186; and 7,402,609 are valid and enforceable, and have been infringed under 35 U.S.C. § 271(e)(2) by Watson's submission to the FDA of its ANDA No. 202526;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Watson's ANDA Product, or any other drug product that infringes or the use of which infringes United States Patent No. 5,641,805 or United States Patent No. 6,995,186 or United States Patent No. 7,402,609 be not earlier than the latest of the expiration dates of those patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson's ANDA product, or any other drug product whose use is covered by United States Patent No. 5,641,805, prior to the expiration of United States Patent No. 5,641,805, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson's ANDA product, or any other drug product

covered by or whose use is covered by United States Patent No. 6,995,186, prior to the expiration of United States Patent No. 6,995,186, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson's ANDA product, or any other drug product covered by or whose use is covered by United States Patent No. 7,402,609, prior to the expiration of United States Patent No. 7,402,609, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A judgment declaring that the use of Watson's ANDA Product, or any other drug product whose use is covered by United States Patent No. 5,641,805, will infringe that patent, and that the commercial manufacture, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product whose use is covered by United States Patent No. 5,641,805, will induce infringement of, and contribute to the infringement by others of, that patent;

(g) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 6,995,186, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent;

(h) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 7,402,609, will infringe and will induce the infringement of that patent;

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

(j) Costs and expenses in this action; and

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

Respectfully submitted,

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