

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

FILED
U.S. DISTRICT COURT
INDIANAPOLIS DIVISION

2013 SEP 12 AM 9:03

SOUTHERN DISTRICT
OF INDIANA
LAURA A. BEIGER
CLERK

ALCON RESEARCH, LTD., and
ALCON PHARMACEUTICALS LTD.,

Plaintiffs,

v.

WOCKHARDT LIMITED,
WOCKHARDT BIO AG,
WOCKHARDT BIO LTD.,
and WOCKHARDT USA, LLC,

Defendants.

1 : 13 -cv- 1452 SEB -MD

Civil Action No. _____

COMPLAINT

Plaintiffs Alcon Research, Ltd. and Alcon Pharmaceuticals Ltd., (collectively “Alcon”), 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 Wockhardt’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. 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. Upon information and belief, defendant Wockhardt Limited is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. Upon information and belief, defendant Wockhardt Bio AG is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. Upon information and belief, Wockhardt Bio AG is a wholly owned subsidiary of Wockhardt Limited. Upon information and belief, Wockhardt Bio AG is also known as Wockhardt Bio Ltd. Upon information and belief, Wockhardt Bio AG was formerly known as Wockhardt EU Operations (Swiss) AG.

6. Upon information and belief, defendant Wockhardt Bio Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. Upon information and belief, Wockhardt Bio Ltd. is a wholly owned subsidiary of Wockhardt Limited. Upon information and belief, Wockhardt Bio Ltd. is also known as Wockhardt Bio AG.

7. Upon information and belief, defendant Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Upon information and belief, Wockhardt USA LLC is an indirect, wholly owned subsidiary of Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt Limited.

8. Wockhardt Limited, Wockhardt Bio AG, Wockhardt Bio Ltd. and

Wockhardt USA, LLC, are collectively referred to herein as "Wockhardt."

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. Wockhardt Limited is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt Limited itself and through its wholly owned subsidiaries, Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt USA, LLC, has purposely availed itself of the benefits and protections of Indiana's laws such that it should reasonably anticipate being haled into court in this District.

11. Upon information and belief, Wockhardt Limited is a generic pharmaceutical company that, on its own and/or through its wholly owned subsidiaries and agents, Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt USA, LLC, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Indiana and the Southern District of Indiana and therefore transacts business within the State of Indiana and the Southern District of Indiana related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana.

12. Upon information and belief, Wockhardt Limited earns revenue from the distribution in the State of Indiana and the Southern District of Indiana by Wockhardt USA, LLC of generic pharmaceutical products that are manufactured by Wockhardt Bio AG, Wockhardt Bio Ltd. and/or Wockhardt USA, LLC, for which Wockhardt Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs.

13. Wockhardt Limited is subject to jurisdiction in the State of Indiana and the

Southern District of Indiana on the basis of its inducement of Wockhardt Bio AG's, Wockhardt Bio Ltd.'s and/or Wockhardt USA, LLC's acts of infringement in the State of Indiana and the Southern District of Indiana.

14. Wockhardt Limited is subject to personal jurisdiction in the State of Indiana and the Southern District of Indiana because, on information and belief, it controls and dominates Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt USA, LLC, and therefore the activities of Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt USA, LLC in this District are attributed to Wockhardt Limited.

15. Wockhardt Bio AG and Wockhardt Bio Ltd. are subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt Bio AG and Wockhardt Bio Ltd. have purposely availed themselves of the benefits and protections of Indiana's laws such that they should reasonably anticipate being haled into court in this District.

16. Upon information and belief, Wockhardt Bio AG and Wockhardt Bio Ltd., on behalf of and as the agents of Wockhardt Limited and/or through Wockhardt USA, LLC, develop, manufacture, market, sell, and/or offer to sell generic pharmaceutical products throughout the United States, including in the State of Indiana and the Southern District of Indiana and therefore transact business within the State of Indiana and the Southern District of Indiana related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana.

17. Upon information and belief, Wockhardt Bio AG and Wockhardt Bio Ltd. earn revenue from the distribution in the State of Indiana and the Southern District of Indiana by Wockhardt USA, LLC of generic pharmaceutical products that are manufactured by Wockhardt

Bio AG, Wockhardt Bio Ltd. and/or Wockhardt USA, LLC, for which Wockhardt Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs.

18. Wockhardt Bio AG and Wockhardt Bio Ltd. are subject to jurisdiction in the State of Indiana and the Southern District of Indiana on the basis of their inducement of Wockhard USA, LLC's acts of infringement in the State of Indiana and the Southern District of Indiana.

19. Wockhardt USA, LLC is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt USA, LLC, has purposely availed itself of the benefits and protections of Indiana's laws such that it should reasonably anticipate being haled into court in this District.

20. Upon information and belief, Wockhardt USA, LLC, on behalf of and as the agent of Wockhardt Limited, Wockhard Bio AG and Wockhardt Bio Ltd., develops, manufactures, imports, markets, offers for sale, and/or sells generic pharmaceutical products throughout the United States, including in the State of Indiana and the Southern District of Indiana and therefore transacts business within the State of Indiana and the Southern District of Indiana related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana.

21. Upon information and belief, Wockhardt USA, LLC earns revenue from the distribution in the State of Indiana and the Southern District of Indiana of generic pharmaceutical products that are manufactured by Wockhardt Bio AG, Wockhardt Bio Ltd. and/or Wockhardt USA, LLC, for which Wockhardt Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs.

22. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt USA, LLC are part of a vertically integrated and unified organization. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, Wockhardt Bio Ltd., and Wockhardt USA, LLC will act in concert to manufacture, import, distribute, offer for sale and sell the products that are the subject of ANDA No. 204856 (“Wockhardt’s ANDA Product”) throughout the United States, including within the State of Indiana and the Southern District of Indiana.

23. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, Wockhardt Bio Ltd., and/or Wockhardt USA, LLC share common employees, officers and directors, and have entered into one or more contracts for the manufacture, importation, distribution, offer for sale, and/or sale of generic pharmaceutical products throughout the United States, including in the State of Indiana and the Southern District of Indiana, which were not negotiated at arm’s length.

24. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, Wockhardt Bio Ltd. and Wockhardt USA, LLC participated in, contributed to, aided, abetted and/or induced the submission by Wockhardt Bio AG and/or Wockhardt Bio Ltd. to the U.S. Food and Drug Administration (“FDA”) of ANDA No. 204856, the ANDA at issue in this litigation.

25. Wockhardt Limited and Wockhardt USA, LLC both have previously consented to personal jurisdiction in this District. Wockhardt Limited and Wockhardt USA, LLC have affirmatively availed themselves of the Courts of this District by asserting counterclaims in previous litigation in the Southern District of Indiana.

COUNT I - INFRINGEMENT OF THE '186 PATENT

26. Plaintiffs incorporate each of the preceding paragraphs 1-25 as if fully set forth herein.

27. The '186 patent, entitled "Olopatadine Formulations for Topical Administration" (Exhibit A 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.

28. 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 0.17-0.62% (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.

29. 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.

30. The '186 patent was assigned to, and is now owned by, Alcon Pharmaceuticals Ltd.

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

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

33. 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.

34. By letter dated July 30, 2013 (the "Notice Letter"), Wockhardt notified Plaintiffs that Wockhardt Bio Ltd. had submitted to the FDA ANDA No. 204856 for Wockhardt'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 Wockhardt's ANDA Product prior to the expiration of, *inter alia*, the '186 patent.

35. In the Notice Letter, Wockhardt also notified Plaintiffs that, as part of its ANDA, Wockhardt 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, Wockhardt submitted ANDA No. 204856 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 Wockhardt's ANDA Product.

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

37. Wockhardt has knowledge of the '186 patent.

38. Wockhardt's submission of ANDA No. 204856 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Wockhardt'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).

39. Upon information and belief, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 204856.

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

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

42. Upon information and belief, Wockhardt 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.

43. Upon information and belief, Wockhardt knows that Wockhardt's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '186 patent, and that Wockhardt's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Wockhardt plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 204856.

44. Notwithstanding Wockhardt's knowledge of the claims of the '186 patent,

Wockhardt has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Wockhardt's ANDA Product with its product labeling following upon FDA approval of ANDA No. 204856 prior to the expiration of the '186 patent.

45. The foregoing actions by Wockhardt 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.

46. Upon information and belief, Wockhardt 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.

47. Unless Wockhardt 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 II - INFRINGEMENT OF THE '609 PATENT

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth herein.

49. The '609 patent, entitled "Olopatadine Formulations for Topical Administration" (Exhibit B 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.

50. 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-1; 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.

51. The '609 patent was assigned to, and is now owned by, Alcon Pharmaceuticals Ltd.

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

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

54. 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.

55. In the Notice Letter, Wockhardt notified Plaintiffs that Wockhardt Bio Ltd. had submitted to the FDA ANDA No. 204856 for Wockhardt'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 Wockhardt's ANDA Product prior to the expiration of, *inter alia*, the '609 patent.

56. In the Notice Letter, Wockhardt also notified Plaintiffs that, as part of its ANDA, Wockhardt 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, Wockhardt submitted ANDA No. 204856 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 Wockhardt's ANDA Product.

57. Wockhardt's ANDA Product is covered by the claim of the '609 patent.

58. Wockhardt has knowledge of the '609 patent.

59. Wockhardt's submission of ANDA No. 204856 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Wockhardt'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).

60. Upon information and belief, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 204856.

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

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

63. Upon information and belief, Wockhardt 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.

64. Notwithstanding Wockhardt's knowledge of the claims of the '609 patent, Wockhardt has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Wockhardt's ANDA Product with its product labeling following upon FDA approval of ANDA No. 204856 prior to the expiration of the '609 patent.

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

66. Upon information and belief, Wockhardt 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.

67. Unless Wockhardt 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 III - DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '186 PATENT**

68. Plaintiffs incorporate each of the preceding paragraphs 1-67 as if fully set forth herein.

69. 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 Wockhardt on the other regarding Wockhardt's infringement, active inducement of infringement, and contribution to the infringement by others of the '186 patent.

70. 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 0.17-0.62% (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.

71. 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.

72. In the Notice Letter described in paragraph 34 above, Wockhardt notified Plaintiffs that Wockhardt Bio Ltd. had submitted ANDA No. 204856 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 Wockhardt's ANDA Product prior to the expiration of, *inter alia*, the '186 patent.

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

74. Upon information and belief, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 204856.

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

76. The manufacture, use, sale, offer for sale, or importation of Wockhardt's

ANDA Product would infringe one or more claims of the '186 patent.

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

78. Upon information and belief, Wockhardt 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.

79. Upon information and belief, Wockhardt knows that Wockhardt's ANDA Product and its product labeling are especially made or adapted for use in infringing the '186 patent, that Wockhardt's ANDA Product is not a staple article or commodity of commerce, and that Wockhardt's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Wockhardt plans and intends to, and will, contribute to infringement of the '186 patent immediately and imminently upon approval of ANDA No. 204856.

80. Notwithstanding Wockhardt's knowledge of the claims of the '186 patent, Wockhardt has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Wockhardt's ANDA Product with its product labeling following upon FDA approval of ANDA No. 204856 prior to the expiration of the '186 patent.

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

82. Upon information and belief, Wockhardt 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.

83. Unless Wockhardt 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.

84. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Wockhardt'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 IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '609 PATENT**

85. Plaintiffs incorporate each of the preceding paragraphs 1-84 as if fully set forth herein.

86. 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 Wockhardt on the other regarding Wockhardt's infringement and active inducement of infringement of the '609 patent.

87. 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-1; 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.

88. In the Notice Letter described in paragraph 34 above, Wockhardt notified Plaintiffs that Wockhardt Bio Ltd. had submitted ANDA No. 204856 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 Wockhardt's ANDA Product prior to the expiration of, *inter alia*, the '609 patent.

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

90. Upon information and belief, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 204856.

91. Wockhardt's ANDA Product is covered by the claim of the '609 patent.

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

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

94. Upon information and belief, Wockhardt 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.

95. Notwithstanding Wockhardt's knowledge of the claim of the '609 patent,

Wockhardt has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Wockhardt's ANDA Product with its product labeling following upon FDA approval of ANDA No. 204856 prior to the expiration of the '609 patent.

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

97. Upon information and belief, Wockhardt 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.

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

99. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Wockhardt'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. 6,995,186 and 7,402,609 are valid and enforceable, and have been infringed under 35 U.S.C. § 271(e)(2) by Wockhardt's submission to the FDA of its ANDA No. 204856;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Wockhardt's ANDA Product, or any other drug product that infringes or the use of which infringes 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 Wockhardt, and all persons acting in concert with Wockhardt, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Wockhardt'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;

(d) A preliminary and permanent injunction enjoining Wockhardt, and all persons acting in concert with Wockhardt, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Wockhardt'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;

(e) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Wockhardt'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;

(f) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Wockhardt'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;

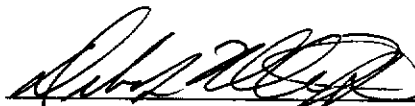
(g) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

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

Respectfully submitted,

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