IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON INC. and ALCON LABORATORIES, INC., *Plaintiffs*, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC., *Defendants*.	)	Civil Action No. _____

COMPLAINT

Plaintiffs Alcon Inc. and Alcon Laboratories, Inc. (collectively, "Alcon"), by their attorneys, file this Complaint for patent infringement and declaratory judgment against Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), and allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Aurobindo'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® Once-Daily Relief 0.7% ophthalmic solution ("PATADAY® Once-Daily"), a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent Nos. 8,791,154 (the "'154 patent") and 9,533,053 (the "'053 patent," and collectively, "the patents-in-suit").

2. By letter dated September 12, 2022 (the "Notice Letter"), counsel for Aurobindo Pharma Limited, notified Alcon that it had submitted to the FDA an ANDA, No.

217710, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic olopatadine hydrochloride ophthalmic solution/drops (Eq. 0.7% base) ("Aurobindo's ANDA Product") prior to the expiration of the '154 patent and '053 patent. Upon information and belief, Aurobindo's ANDA Product is a drug product that is a generic version of PATADAY® Once-Daily, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

3. Plaintiff Alcon Inc. is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Louis-d'Affry 6, 1701 Fribourg, Switzerland.

4. Plaintiff Alcon Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6201 South Freeway, Fort Worth, Texas 76134. Alcon Laboratories, Inc. is a direct, wholly owned subsidiary of Alcon Inc.

5. On information and belief, defendant Aurobindo Pharma Ltd. is a company organized and existing under the laws of the Republic of India with a principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Aurobindo Pharma Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma USA, Inc., for the U.S. market, including in the State of Delaware.

6. On information and belief, defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place

of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, including in the State of Delaware.

7. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. and is controlled and/or dominated by Aurobindo Pharma Ltd.

8. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit Aurobindo's ANDA to the FDA.

JURISDICTION AND VENUE

9. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b), 2201, and 2202.

10. This Court has personal jurisdiction over Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.

11. Aurobindo Pharma, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Aurobindo Pharma, Ltd., itself and through its wholly-owned subsidiary Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma, Ltd., itself and through its wholly-owned subsidiaries Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Aurobindo Pharma,

Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma, Ltd.

12. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Alcon's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. On information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Aurobindo's ANDA Product at issue. On information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. together participated in, assisted, and cooperated in the acts complained of herein.

14. On information and belief, Aurobindo knows and intends that following any approval of Aurobindo's ANDA No. 217710, Aurobindo will manufacture and import into the United States Aurobindo's ANDA Product and directly or indirectly market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 217710, Aurobindo knows and intends that Aurobindo's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware. On information and belief, following any FDA approval of Aurobindo's ANDA No. 217710, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell Aurobindo's ANDA Product throughout the United States, including within Delaware.

15. Aurobindo has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification 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), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. On information and belief, Aurobindo, with knowledge of the Hatch-Waxman Act process, directed Aurobindo's Notice Letter to, *inter alia*, Alcon Laboratories, Inc., an entity incorporated in Delaware, and alleged in Aurobindo's Notice Letter that all of the patents-in-suit are invalid and/or not infringed. On information and belief, Aurobindo knowingly and deliberately challenged Alcon's patent rights, and knew when it did so that it was triggering the forty-five-day period for Alcon to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because Alcon Laboratories, Inc. is incorporated in Delaware, Alcon suffers injury and consequences from Aurobindo's filing of Aurobindo's ANDA, challenging Alcon's patent rights in Delaware. On information and belief, Aurobindo knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Aurobindo has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Aurobindo's Notice Letter to Alcon Laboratories, Inc., a Delaware corporation, that it would be sued in Delaware for patent infringement.

18. In addition, this Court has personal jurisdiction over Aurobindo because Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Novartis Pharmaceuticals Corp. v. Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.*, Case No. 20-1426-GBW, D.I. 41 (D. Del. Sept. 16, 2021); *Merck Sharp & Dohme Corp. v. Aurobindo Pharma, Ltd., and Aurobindo Pharma USA Inc.*, Case No. 20-1099-RGA, D.I. 8 (D. Del. Sept. 16, 2020); *Novartis Pharmaceuticals Co. v. Alkem Laboratories, Ltd. et al.*, Case 19-1979-LPS, D.I. 54 (D. Del. Feb. 6, 2020); *Millennium Pharmaceuticals, Inc. v. Aurobindo Pharma USA Inc. and Aurobindo Pharma, Ltd.*, Case No. 19-471-CFC-SRF, D.I. 9 (D. Del. Apr. 9, 2019); *Allergan Sales LLC et al v. Aurobindo Pharma USA Inc. and Aurobindo Pharma, Ltd.*, Case No. 18-118-GMS, D.I. 8 (D. Del. May 2, 2018); *AstraZeneca AB v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc.*, Case No. 14-1469, D.I. 8 (D. Del. Dec. 31, 2014).

19. Upon information and belief, if Aurobindo's ANDA is approved, Aurobindo will directly or indirectly manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States, including in Delaware, consistent with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Aurobindo regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Alcon's patents in the event that Aurobindo's ANDA Product is approved before the patents expire.

20. On information and belief, Aurobindo derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Aurobindo and/or for which Aurobindo Pharma, Ltd. or Aurobindo Pharma USA, Inc. is the named applicant on approved ANDAs. On information and belief, various products for which Aurobindo Pharma, Ltd. or Aurobindo Pharma USA, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

21. Venue is proper in this district as to Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district as to Aurobindo Pharma, Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

23. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

24. PATADAY® Once-Daily is an ophthalmic solution used for the treatment of the symptoms of ocular allergies, including allergic conjunctivitis.

25. Alcon Laboratories, Inc. is the owner of NDA 206276 for PATADAY® Once-Daily.

26. PATADAY® Once-Daily contains at least .67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least .5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

27. Upon information and belief, Aurobindo's ANDA Product is a generic version of Alcon's PATADAY® Once-Daily.

28. On information and belief, Aurobindo's ANDA Product is not publicly available, nor is ANDA No. 217710 accessible to the public.

29. In Aurobindo's Notice Letter, Aurobindo included an Offer of Confidential Access to portions of ANDA No. 217710. The offer, however, was subject to various unreasonably restrictive conditions.

30. Alcon is filing this Complaint within forty-five days of receipt of Aurobindo's Notice Letter.

COUNT I – INFRINGEMENT OF THE '154 PATENT

31. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

32. The '154 patent, entitled "High Concentration Olopatadine Ophthamalic Composition" (Exhibit A hereto), was duly and legally issued on July 29, 2014.

33. Alcon Inc. is the owner and assignee of the '154 patent.

34. The '154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

35. The '154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least .5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

36. Alcon will be substantially and irreparably damaged by infringement of the '154 patent.

37. PATADAY® Once-Daily, and the use of PATADAY® Once-Daily, are covered by one or more claims of the ’154 patent, and the ’154 patent has been listed in connection with that drug product in the FDA’s Orange Book.

38. In its Notice Letter, Aurobindo notified Alcon that it had submitted to the FDA ANDA No. 217710. The purpose of the submission 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 Aurobindo’s ANDA Product prior to the expiration of the ’154 patent.

39. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo 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 ’154 patent. Upon information and belief, Aurobindo submitted ANDA No. 217710 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’154 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product.

40. Aurobindo’s ANDA Product and the use of Aurobindo’s ANDA Product are covered by one or more claims of the ’154 patent, including at least claim 1 and claim 12.

41. In the Notice Letter, Aurobindo did not contest the infringement of claims 1-6, 8-10 and 12-27 of the ’154 patent.

42. According to the Notice Letter, Aurobindo’s ANDA contains bioavailability and bioequivalence data comparing Aurobindo’s ANDA Product to PATADAY® Once-Daily.

43. According to the Notice Letter, Aurobindo's ANDA Product is an ophthalmic solution that comprises at least .67 w/v% olopatadine but no greater than 1.0 w/v% olopatadine dissolved in the solution.

44. According to the Notice Letter, Aurobindo's ANDA Product contains 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500, 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone, at least .5 w/v% but no greater than 2.0 w/v% hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

45. Aurobindo has knowledge of the '154 patent.

46. Aurobindo's submission of ANDA No. 217710 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '154 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of ANDA No. 217710.

48. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

49. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

50. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the ’154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

51. Upon information and belief, Aurobindo knows that Aurobindo’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’154 patent, that Aurobindo’s ANDA Product is not a staple article or commodity of commerce, and that Aurobindo’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the ’154 patent immediately and imminently upon approval of ANDA No. 217710.

52. Notwithstanding Aurobindo’s knowledge of the claims of the ’154 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo’s ANDA Product with its product labeling following upon FDA approval of ANDA No. 217710 prior to the expiration of the ’154 patent.

53. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’154 patent, active inducement of the ’154 patent, and contribution to the infringement by others of the ’154 patent.

54. Upon information and belief, Aurobindo has acted with full knowledge of the ’154 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’154 patent, active inducement of the ’154 patent, and/or contribution to the infringement by others of the ’154 patent.

55. Unless Aurobindo is enjoined from infringing the '154 patent, actively inducing infringement of the '154 patent, and contributing to the infringement by others of the '154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '154 PATENT

56. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

57. 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 Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '154 patent.

58. The '154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

59. The '154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least .5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

60. In the Notice Letter, Aurobindo notified Alcon that Aurobindo had submitted ANDA No. 217710 to the FDA. 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 Aurobindo's ANDA Product prior to the expiration of the '154 patent.

61. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo 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).

62. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of ANDA No. 217710.

63. Aurobindo's ANDA Product and use of Aurobindo's ANDA Product is covered by one or more claims of the '154 patent, including at least claim 1 and claim 12.

64. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

65. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, Aurobindo's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

66. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

67. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its product labeling are especially made or adapted for use in infringing the '154 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 217710.

68. Notwithstanding Aurobindo's knowledge of the claims of the '154 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of ANDA No. 217710 prior to the expiration of the '154 patent.

69. The foregoing actions by Aurobindo will constitute infringement of, active inducement of infringement of, and contribute to the infringement by others of the '154 patent.

70. Upon information and belief, Aurobindo has acted with full knowledge of the '154 patent and without a reasonable basis for believing that it would not be liable for infringement of the '154 patent, active inducement of infringement of the '154 patent, and contribution to the infringement by others of the '154 patent.

71. Unless Aurobindo is enjoined from infringing, inducing infringement of, and contributing to the infringement by others of, the '154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

72. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product which is

covered by or whose use is covered by United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent.

COUNT III – INFRINGEMENT OF THE '053 PATENT

73. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

74. The '053 patent, entitled "High Concentration Olopatadine Ophthalmic Composition" (Exhibit B hereto), was duly and legally issued on January 3, 2017.

75. Alcon Inc. is the owner and assignee of the '053 patent.

76. The '053 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin, and hydroxypropyl-γ-cyclodextrin; and water.

77. The '053 patent also claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; benzalkonium chloride; hydroxypropylmethyl cellulose; and water.

78. Alcon will be substantially and irreparably damaged by infringement of the '053 patent.

79. PATADAY® Once-Daily, and the use of PATADAY® Once-Daily, are covered by one or more claims of the ’053 patent, and the ’053 patent has been listed in connection with that drug product in the FDA’s Orange Book.

80. In its Notice Letter, Aurobindo notified Alcon that it had submitted to the FDA ANDA No. 217710. The purpose of the submission 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 Aurobindo’s ANDA Product prior to the expiration of the ’053 patent.

81. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo 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 ’053 patent. Upon information and belief, Aurobindo submitted ANDA No. 217710 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’053 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product.

82. Aurobindo’s ANDA Product and the use of Aurobindo’s ANDA Product are covered by one or more claims of the ’053 patent, including at least claim 1 and claim 8.

83. In the Notice Letter, Aurobindo did not contest the infringement of claims 1–13 of the ’053 patent.

84. According to the Notice Letter, Aurobindo’s ANDA contains bioavailability and bioequivalence data comparing Aurobindo’s ANDA Product to PATADAY® Once-Daily.

85. According to the Notice Letter, Aurobindo's ANDA Product is an ophthalmic solution that comprises at least .67 w/v% olopatadine but no greater than 1.0 w/v% olopatadine dissolved in the solution.

86. According to the Notice Letter, Aurobindo's ANDA Product contains PEG having a molecular weight of 200 to 800, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, hydroyxypropylmethyl cellulose, and water.

87. Aurobindo has knowledge of the '053 patent.

88. Aurobindo's submission of ANDA No. 217710 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '053 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

89. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of ANDA No. 217710.

90. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

91. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by Aurobindo' proposed product labeling would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

92. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the ’053 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

93. Notwithstanding Aurobindo’ knowledge of the claims of the ’053 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo’s ANDA Product with its product labeling following upon FDA approval of ANDA No. 217710 prior to the expiration of the ’053 patent.

94. The foregoing actions by Aurobindo constitute and/or will constitute infringement, and active inducement of infringement, of the ’053 patent.

95. Upon information and belief, Aurobindo has acted with full knowledge of the ’053 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’053 patent and/or active inducement of infringement of the ’053 patent.

96. Unless Aurobindo is enjoined from infringing the ’053 patent and actively inducing infringement of the ’053 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’053 PATENT

97. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

98. 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 Aurobindo on the other regarding Aurobindo’ infringement, and active inducement of infringement, of the ’053 patent.

99. The ’053 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin, and hydroxypropyl-γ-cyclodextrin; and water.

100. The ’053 patent also claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; benzalkonium chloride; hydroxypropylmethyl cellulose; and water.

101. In the Notice Letter, Aurobindo notified Alcon that it had submitted ANDA No. 217710 to the FDA. 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 Aurobindo’s ANDA Product prior to the expiration of the ’053 patent.

102. In the Notice Letter, Aurobindo also notified Alcon that, as part of its ANDA, Aurobindo 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).

103. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Product immediately and imminently upon approval of ANDA No. 217710.

104. Aurobindo’s ANDA Product and use of Aurobindo’s ANDA Product is covered by one or more claims of the ’053 patent, including at least claim 1 and claim 8.

105. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

106. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, Aurobindo' proposed product labeling would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

107. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '053 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

108. Notwithstanding Aurobindo' knowledge of the claims of the '053 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of ANDA No. 217710 prior to the expiration of the '053 patent.

109. The foregoing actions by Aurobindo will constitute infringement of, and active inducement of infringement of, the '053 patent.

110. Upon information and belief, Aurobindo has acted with full knowledge of the '053 patent and without a reasonable basis for believing that it would not be liable for infringement of the '053 patent and/or active inducement of infringement of the '053 patent.

111. Unless Aurobindo is enjoined from infringing, and inducing infringement of, the '053 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

112. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product which is

covered by or whose use is covered by United States Patent No. 9,533,053, will infringe, and induce the infringement of, that patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to the FDA of its ANDA No. 217710;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Aurobindo's ANDA Product, or any other drug product that infringes or the use of which infringes the patents-in-suit, be not earlier than the latest of the expiration dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product, or any other drug product covered by or whose use is covered by the patents-in-suit prior to their expiration, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product which is covered by or whose use is covered by the patents-in-suit, prior to their expiration, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent;

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

(f) Costs and expenses in this action;

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

DATED: October 24, 2022

MCCARTER & ENGLISH, LLP

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