IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON INC. and ALCON LABORATORIES, INC., Plaintiffs, v. SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, and ODIN PHARMACEUTICALS, LLC, 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 Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively, "Somerset"), 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 Somerset'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 March 15, 2022 (the "Notice Letter"), Somerset Therapeutics, LLC, notified Alcon that it had submitted to the FDA an ANDA, No. 216499, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic Opthalmic Solution/Drops of Olopatadine Hydrochloride 0.7% ("Somerset's ANDA Product") prior to the expiration of the '154 patent and '053 patent. Upon information and belief, Somerset'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. Upon information and belief, defendant Somerset Therapeutics, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873-4187. Upon information and belief, Somerset Therapeutics, LLC, 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.

6. Upon information and belief, defendant Somerset Pharma, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a principal

place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873-4187. Upon information and belief, Somerset Pharma, LLC, 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. Upon information and belief, defendant Odin Pharmaceuticals, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873-4187. Upon information and belief, Odin Pharmaceuticals, LLC, 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.

8. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC, acted in concert to prepare and submit Somerset'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 each of Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC.

11. This Court has personal jurisdiction over Somerset Therapeutics, LLC. Somerset Therapeutics, LLC, is subject to personal jurisdiction in Delaware because, among other things, it 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, Somerset Therapeutics, LLC, itself and through its affiliates Somerset Pharma, LLC, and Odin

Pharmaceuticals, LLC, 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 systemic and continuous business contacts within the State of Delaware. In addition, Somerset Therapeutics, LLC, is subject to personal jurisdiction in Delaware because, upon information and belief, Somerset Therapeutics, LLC, 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.

12. This Court has personal jurisdiction over Somerset Pharma, LLC. Somerset Pharma, LLC, is subject to personal jurisdiction in Delaware because, among other things, it 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, Somerset Pharma, LLC, itself and through its affiliates Somerset Therapuetics, LLC, and Odin Pharmaceuticals, LLC, 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 systemic and continuous business contacts within the State of Delaware. In addition, Somerset Pharma, LLC, is subject to personal jurisdiction in Delaware because, upon information and belief, Somerset Pharma, LLC, 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.

13. This Court has personal jurisdiction over Odin Pharmaceuticals, LLC. Odin Pharmaceuticals, LLC, is subject to personal jurisdiction in Delaware because, among other

things, it 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, Odin Pharmaceuticals, LLC, itself and through its affiliates Somerset Therapeutics, LLC, and Somerset Pharma, LLC, 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 systemic and continuous business contacts within the State of Delaware. In addition, Odin Pharmaceuticals, LLC, is subject to personal jurisdiction in Delaware because, upon information and belief, Odin Pharmaceuticals, LLC, 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.

14. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC, 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 Somerset's ANDA Product at issue. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC, together participated in, assisted, and cooperated in the acts complained of herein.

15. On information and belief, Somerset knows and intends that following any approval of Somerset's ANDA No. 216499, Somerset will directly or indirectly manufacture, market, sell, and distribute Somerset's ANDA Product throughout the United States, including in

Delaware. On information and belief, following any FDA approval of ANDA No. 216499, Somerset knows and intends that Somerset's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

16. Somerset 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.

17. On information and belief, Somerset, with knowledge of the Hatch-Waxman Act process, directed Somerset's Notice Letter to, *inter alia*, Alcon Laboratories, Inc., an entity incorporated in Delaware, and alleged in Somerset's Notice Letter that all of the patents-in-suit are invalid and/or not infringed. On information and belief, Somerset 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.

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

19. In addition, this Court has personal jurisdiction over Somerset because it has engaged in patent litigation concerning FDA-approved branded drug products in this district, and did not contest personal jurisdiction or venue in this district. *See, e.g.*, 1:16-cv-00392-GMS (D. Del.).

20. Upon information and belief, if Somerset's ANDA is approved, Somerset will directly or indirectly manufacture, market, sell, and/or distribute Somerset's ANDA Product within the United States, including in Delaware, consistent with Somerset's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Somerset 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, Somerset's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Somerset's ANDA Product will be sold by retail outlets 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 Somerset's ANDA Product is approved before the patents expire.

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

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

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

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

FACTUAL BACKGROUND

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

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

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

28. 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.

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

30. On information and belief, Somerset's ANDA Product is not publicly available, nor is ANDA No. 216499 accessible to the public.

31. In Somerset's Notice Letter, Somerset included an Offer of Confidential Access to portions of ANDA No. 216499. The offer, however, was subject to various unreasonably restrictive conditions.

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

COUNT I – INFRINGEMENT OF THE '154 PATENT

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

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

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

36. 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.

37. 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.

38. Alcon will be substantially and irreparably damaged by infringement of the ’154 patent.

39. 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.

40. In its Notice Letter, Somerset notified Plaintiffs that it had submitted to the FDA ANDA No. 216499. 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 Somerset’s ANDA Product prior to the expiration of the ’154 patent.

41. In the Notice Letter, Somerset also notified Plaintiffs that, as part of its ANDA, Somerset 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, Somerset submitted ANDA No. 216499 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 Somerset’s ANDA Product.

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

43. In the Notice Letter, Somerset did not contest the infringement of claims 1-6, 8-10 and 12-27 of the '154 patent.

44. According to the Notice Letter, Somerset's ANDA contains bioavailability and bioequivalence data comparing Somerset's ANDA Product to PATADAY® Once-Daily.

45. According to the Notice Letter, Somerset'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.

46. Upon information and belief, Somerset'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.

47. Somerset has knowledge of the '154 patent.

48. Somerset's submission of ANDA No. 216499 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Somerset'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).

49. Upon information and belief, Somerset will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Somerset's ANDA Product immediately and imminently upon approval of ANDA No. 216499.

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

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

52. Upon information and belief, Somerset 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.

53. Upon information and belief, Somerset knows that Somerset's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '154 patent, that Somerset's ANDA Product is not a staple article or commodity of commerce, and that Somerset's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Somerset plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 216499.

54. Notwithstanding Somerset's knowledge of the claims of the '154 patent, Somerset has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Somerset's ANDA Product with its product labeling following upon FDA approval of ANDA No. 216499 prior to the expiration of the '154 patent.

55. The foregoing actions by Somerset 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.

56. Upon information and belief, Somerset 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.

57. Unless Somerset 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

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

59. 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 Somerset on the other regarding Somerset’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’154 patent.

60. 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.

61. 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.

62. In the Notice Letter, Somerset notified Plaintiffs that Somerset had submitted ANDA No. 216499 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 Somerset's ANDA Product prior to the expiration of the '154 patent.

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

64. Upon information and belief, Somerset will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Somerset's ANDA Product immediately and imminently upon approval of ANDA No. 216499.

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

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

67. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Somerset's ANDA Product in accordance with, and as directed by, Somerset's

proposed product labeling would infringe one or more claims of the ’154 patent, including at least Claim 1 and Claim 12.

68. Upon information and belief, Somerset 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.

69. Upon information and belief, Somerset knows that Somerset’s ANDA Product and its product labeling are especially made or adapted for use in infringing the ’154 patent, that Somerset’s ANDA Product is not a staple article or commodity of commerce, and that Somerset’s ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Somerset plans and intends to, and will, contribute to infringement of the ’154 patent immediately and imminently upon approval of ANDA No. 216499.

70. Notwithstanding Somerset’s knowledge of the claims of the ’154 patent, Somerset has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Somerset’s ANDA Product with its product labeling following FDA approval of ANDA No. 216499 prior to the expiration of the ’154 patent.

71. The foregoing actions by Somerset will constitute infringement of, active inducement of infringement of, and contribute to the infringement by others of the ’154 patent.

72. Upon information and belief, Somerset 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.

73. Unless Somerset 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.

74. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Somerset’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

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

76. The ’053 patent, entitled “High Concentration Olopatadine Ophthalmic Composition” (Exhibit A hereto), was duly and legally issued on January 3, 2017.

77. Alcon Inc. is the owner and assignee of the ’053 patent.

78. 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.

79. 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.

80. Alcon will be substantially and irreparably damaged by infringement of the ’053 patent.

81. 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.

82. In its Notice Letter, Somerset notified Plaintiffs that it had submitted to the FDA ANDA No. 216499. 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 Somerset’s ANDA Product prior to the expiration of the ’053 patent.

83. In the Notice Letter, Somerset also notified Plaintiffs that, as part of its ANDA, Somerset 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, Somerset submitted ANDA No. 216499 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 Somerset’s ANDA Product.

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

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

86. According to the Notice Letter, Somerset's ANDA contains bioavailability and bioequivalence data comparing Somerset's ANDA Product to PATADAY® Once-Daily.

87. According to the Notice Letter, Somerset'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.

88. Upon information and belief, Somerset's ANDA Product contains PEG having a molecular weight of 200 to 800, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, hydroyxypropylmethyl cellulose, and water.

89. Somerset has knowledge of the '053 patent.

90. Somerset's submission of ANDA No. 216499 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Somerset'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).

91. Upon information and belief, Somerset will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Somerset's ANDA Product immediately and imminently upon approval of ANDA No. 216499.

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

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

94. Upon information and belief, Somerset 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.

95. Notwithstanding Somerset’ knowledge of the claims of the ’053 patent, Somerset has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Somerset’s ANDA Product with its product labeling following upon FDA approval of ANDA No. 216499 prior to the expiration of the ’053 patent.

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

97. Upon information and belief, Somerset 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.

98. Unless Somerset 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

99. Alcon incorporates each of the preceding paragraphs 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 Somerset on the other regarding Somerset’ infringement, and active inducement of infringement, of the ’053 patent.

101. 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.

102. 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.

103. In the Notice Letter, Somerset notified Plaintiffs that it had submitted ANDA No. 216499 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 Somerset’s ANDA Product prior to the expiration of the ’053 patent.

104. In the Notice Letter, Somerset also notified Plaintiffs that, as part of its ANDA, Somerset 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, Somerset will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Somerset’s ANDA Product immediately and imminently upon approval of ANDA No. 216499.

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

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

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

109. Upon information and belief, Somerset 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.

110. Notwithstanding Somerset' knowledge of the claims of the '053 patent, Somerset has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Somerset's ANDA Product with its product labeling following FDA approval of ANDA No. 216499 prior to the expiration of the '053 patent.

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

112. Upon information and belief, Somerset 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.

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

114. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Somerset'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 Somerset's submission to the FDA of its ANDA No. 216499;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Somerset'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 Somerset, and all persons acting in concert with Somerset, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Somerset'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 Somerset'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.

Respectfully submitted,

OF COUNSEL:

Christopher J. Mandernach
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000
(202) 434-5029 (Facsimile)
cmandernach@wc.com

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MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs Alcon Inc. and Alcon Laboratories, Inc.