IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON INC. and ALCON LABORATORIES, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
GLAND PHARMA LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Alcon Inc. and Alcon Laboratories, Inc. (collectively, "Alcon"), by their attorneys, file this Complaint for patent infringement and declaratory judgment against Gland Pharma Limited ("Gland"), 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 Gland'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 February 7, 2023 (the "Notice Letter"), counsel for Gland notified Alcon that it had submitted to the FDA an ANDA, No. 213514, 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) ("Gland's ANDA Product") prior to the expiration of the '154 patent and '053 patent. Upon information and belief, Gland'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, Gland is a corporation organized and existing under the laws of India, having its principal place of business at Survey No. 143-148, 150 & 151, Near Gandimaisamma Cross Roads, D.P. Pally, Dundigal Gandimaisamma Mandal, Medchal-Malkajgiri District, Hyderabad 500043, Telangana, India. On information and belief, Gland is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market, including in the State of Delaware.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Gland.

8. Gland 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, Gland 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.

9. On information and belief, Gland knows and intends that following any approval of Gland's ANDA No. 213514, Gland will manufacture and import into the United States Gland's ANDA Product and directly or indirectly market, sell, and distribute Gland's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 213514, Gland knows and intends that Gland'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 Gland's ANDA No. 213514, Gland will distribute and sell Gland's ANDA Product throughout the United States, including within Delaware.

10. Gland 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.

11. On information and belief, Gland, with knowledge of the Hatch-Waxman Act process, directed Gland's Notice Letter to, *inter alia*, Alcon Laboratories, Inc., an entity

incorporated in Delaware, and alleged in Gland's Notice Letter that all of the patents-in-suit are invalid and/or not infringed. On information and belief, Gland 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.

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

13. In addition, this Court has personal jurisdiction over Gland because Gland regularly engages in patent litigation concerning FDA-approved branded drug products in this district, does not contest personal jurisdiction in this district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Astellas US LLC et al. v. Gland Pharma Limited*, 1:20-cv-00347-CFC (D. Del.) at D.I. 10.

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

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

16. Venue is proper in this district as to Gland pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Gland 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

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

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

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

20. 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.

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

22. On information and belief, Gland's ANDA Product is not publicly available, nor is ANDA No. 213514 accessible to the public.

23. In Gland's Notice Letter, Gland included an Offer of Confidential Access to portions of ANDA No. 213514. The offer, however, was subject to various unreasonably restrictive conditions.

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

COUNT I – INFRINGEMENT OF THE '154 PATENT

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

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

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

28. 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.

29. 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.

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

31. 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.

32. In its Notice Letter, Gland notified Alcon that it had submitted to the FDA ANDA No. 213514. 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 Gland’s ANDA Product prior to the expiration of the ’154 patent.

33. In the Notice Letter, Gland also notified Alcon that, as part of its ANDA, Gland 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, Gland submitted ANDA No. 213514 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 Gland's ANDA Product.

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

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

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

37. According to the Notice Letter, Gland'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.

38. According to the Notice Letter, Gland'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.

39. Gland has knowledge of the '154 patent.

40. Gland's submission of ANDA No. 213514 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Gland'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).

41. Upon information and belief, Gland will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Gland's ANDA Product immediately and imminently upon approval of ANDA No. 213514.

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

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

44. Upon information and belief, Gland 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.

45. Upon information and belief, Gland knows that Gland's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '154 patent, that Gland's ANDA Product is not a staple article or commodity of commerce, and that Gland's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Gland plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 213514.

46. Notwithstanding Gland's knowledge of the claims of the '154 patent, Gland has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Gland's ANDA Product with its product labeling following upon FDA approval of ANDA No. 213514 prior to the expiration of the '154 patent.

47. The foregoing actions by Gland 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.

48. Upon information and belief, Gland 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.

49. Unless Gland 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

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

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

52. 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.

53. 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.

54. In the Notice Letter, Gland notified Alcon that Gland had submitted ANDA No. 213514 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 Gland's ANDA Product prior to the expiration of the '154 patent.

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

56. Upon information and belief, Gland will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Gland's ANDA Product immediately and imminently upon approval of ANDA No. 213514.

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

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

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

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

60. Upon information and belief, Gland 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.

61. Upon information and belief, Gland knows that Gland’s ANDA Product and its product labeling are especially made or adapted for use in infringing the ’154 patent, that Gland’s ANDA Product is not a staple article or commodity of commerce, and that Gland’s ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Gland plans and intends to, and will, contribute to infringement of the ’154 patent immediately and imminently upon approval of ANDA No. 213514.

62. Notwithstanding Gland’s knowledge of the claims of the ’154 patent, Gland has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Gland’s ANDA Product with its product labeling following FDA approval of ANDA No. 213514 prior to the expiration of the ’154 patent.

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

64. Upon information and belief, Gland 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.

65. Unless Gland 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.

66. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Gland'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

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

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

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

70. 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.

71. 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.

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

73. 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.

74. In its Notice Letter, Gland notified Alcon that it had submitted to the FDA ANDA No. 213514. 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 Gland’s ANDA Product prior to the expiration of the ’053 patent.

75. In the Notice Letter, Gland also notified Alcon that, as part of its ANDA, Gland 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, Gland submitted ANDA No. 213514 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 Gland’s ANDA Product.

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

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

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

79. According to the Notice Letter, Gland'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.

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

81. Gland has knowledge of the '053 patent.

82. Gland's submission of ANDA No. 213514 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Gland'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).

83. Upon information and belief, Gland will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Gland's ANDA Product immediately and imminently upon approval of ANDA No. 213514.

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

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

86. Upon information and belief, Gland 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.

87. Notwithstanding Gland’s knowledge of the claims of the ’053 patent, Gland has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Gland’s ANDA Product with its product labeling following upon FDA approval of ANDA No. 213514 prior to the expiration of the ’053 patent.

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

89. Upon information and belief, Gland 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.

90. Unless Gland 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

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

92. 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 Gland on the other regarding Gland’s infringement, and active inducement of infringement, of the ’053 patent.

93. 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.

94. 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.

95. In the Notice Letter, Gland notified Alcon that it had submitted ANDA No. 213514 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 Gland’s ANDA Product prior to the expiration of the ’053 patent.

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

97. Upon information and belief, Gland will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Gland’s ANDA Product immediately and imminently upon approval of ANDA No. 213514.

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

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

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

101. Upon information and belief, Gland 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.

102. Notwithstanding Gland's knowledge of the claims of the '053 patent, Gland has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Gland's ANDA Product with its product labeling following FDA approval of ANDA No. 213514 prior to the expiration of the '053 patent.

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

104. Upon information and belief, Gland 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.

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

106. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Gland'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 Gland's submission to the FDA of its ANDA No. 213514;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Gland'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 Gland, and all persons acting in concert with Gland, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland'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 Gland'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: March 20, 2023

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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