IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff,* v. SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES INC., and SUN PHARMA GLOBAL FZE *Defendants.*	C.A. No. 21-1656 (MN)

FIRST AMENDED COMPLAINT AGAINST DEFENDANTS SUN PHARMACEUTICALS INDUSTRIES LTD., SUN PHARMACEUTICALS INDUSTRIES INC. AND SUN PHARMA GLOBAL FZE

Plaintiff Novartis Pharmaceuticals Corporation (herein, "Novartis") files this First Amended Complaint for patent infringement against Sun Pharmaceuticals Industries Ltd., Sun Pharmaceuticals Industries Inc. and Sun Pharma Global FZE (collectively, "Sun"), and by its attorneys, hereby alleges 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 Sun's submission of an Abbreviated New Drug New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of XIIDRA® (lifitegrast ophthalmic solution) 5% prior to the expiration of U.S. Patent No. 7,314,938 ("the '938

patent"); U.S. Patent No. 7,745,460 ("the '460 patent"); U.S. Patent No. 7,790,743 ("the '743 patent"); U.S. Patent No. 7,928,122 ("the '122 patent"); U.S. Patent No. 9,216,174 ("the '174 patent"); U.S. Patent No. 10,124,000 ("the '000 patent"); U.S. Patent No. 8,084,047 ("the '047 patent"); U.S. Patent No. 8,592,450 ("the '450 patent"); U.S. Patent No. 8,168,655 ("the '655 patent"); U.S. Patent No. 8,367,701 ("the '701 patent"); U.S. Patent No. 9,447,077 ("the '077 patent"); U.S. Patent No. 8,927,574 ("the '574 patent"); U.S. Patent No. 9,353,088 ("the '088 patent"); U.S. Patent No. 9,890,141 ("the '141 patent"); U.S. Patent No. 9,085,553 ("the '553 patent"); and U.S. Patent No. 11,058,677 ("the '677 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Sun Pharmaceuticals Industries Ltd. notified Novartis by letter dated September 16, 2020 ("Sun's First Notice Letter") that it had submitted to the FDA ANDA No. 215126 ("Sun's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of lifitegrast ophthalmic solution 5% ("Sun's ANDA Product") prior to the expiration of the '574 patent, the '088 patent, the '141 patent, and the '553 patent. By letter dated October 11, 2021, Sun provided Novartis with a second notice letter ("Sun's Second Notice Letter") informing Novartis that it was also seeking approval of its ANDA Product prior to the expiration of the '677 patent. By letter dated July 28, 2022, Sun provided Novartis with a third notice letter ("Sun's Third Notice Letter") informing Novartis that it was also seeking approval of its ANDA product prior to the expiration of the '938 patent, the '460 patent, the '743 patent, the '122 patent, the '174 patent, the '000 patent, the '047 patent, the '450 patent, the '655 patent, the '701 patent, and the '077 patent. Collectively, these notice letters are referred to herein as the "Sun's Notice Letters."

PARTIES

3. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Health Plaza, East Hanover, NJ 07936. Novartis Pharmaceuticals Corporation is the holder of New Drug Application ("NDA") No. 208073 for the manufacture and sale of lifitegrast ophthalmic solution 5%, which has been approved by the FDA.

4. On information and belief, defendant Sun Pharmaceutical Industries, Ltd. is a company organized and existing under the laws of the Republic of India with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. On information and belief, Sun Pharmaceutical Industries Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Sun Pharmaceutical Industries, Inc.

5. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2 Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Pharmaceutical Industries, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

6. On information and belief, defendant Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with places of business at Office #43, Block Y, SAIF Zone, P.O. Box No. 122304, Sharjah, United Arab Emirates, and DMCC Branch, 704 Jumeriah Business Center 1, Cluster G, JLT, P.O. Box No. 643561, Dubai, United Arab Emirates. On information and belief, Sun Pharma Global FZE is in the business of,

among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

7. On information and belief, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE are wholly owned subsidiaries of Sun Pharmaceutical Industries Ltd. and are controlled and/or dominated by Sun Pharmaceutical Industries Ltd.

8. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE acted in concert to prepare and submit Sun's ANDA to the FDA.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over each Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc, and Sun Pharma Global FZE.

11. Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in Delaware because, among other things, Sun Pharmaceutical Industries Ltd., itself and through its wholly-owned subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, 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, Sun Pharmaceutical Industries Ltd., itself and through its wholly-owned subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, 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, Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls Sun Pharmaceutical Industries, Inc. and Sun Global Pharma FZE, and therefore the activities of Sun Pharmaceutical Industries, Inc. and Sun Global Pharma FZE in this jurisdiction are attributed to Sun Pharmaceutical Industries Ltd.

12. Sun Pharmaceutical Industries, 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. Sun Pharmaceutical Industries, 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, Sun Pharmaceutical Industries, 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 Novartis's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. Sun Pharma Global FZE is subject to personal jurisdiction in Delaware because, among other things, Sun Pharma Global FZE 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, Sun Pharma Global FZE 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.

14. On information and belief, Sun knows and intends that following any approval of Sun's ANDA No. 215126, Sun will manufacture and import into the United States Sun's ANDA Product and directly or indirectly market, sell, and distribute Sun's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 215126, Sun knows and intends that Sun'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 Sun's ANDA No. 215126, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE will act in concert to distribute and sell Sun's ANDA Product throughout the United States, including within Delaware.

15. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE 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 Sun's ANDA Product at issue. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE together participated in, assisted, and cooperated in the acts complained of herein.

16. Sun 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, Sun, with knowledge of the Hatch-Waxman Act process, directed Sun's Notice Letters to, inter alia, Novartis Pharmaceuticals Corporation, an entity incorporated in Delaware, and alleged in Sun's Notice Letters that all of the Patents-in-Suit are invalid and/or not infringed. On information and belief, Sun knowingly and deliberately challenged Novartis's patent rights, and knew when it did so that it was triggering the forty-five-day period for Novartis to bring an action for patent infringement under the Hatch-Waxman Act.

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

19. In addition, this Court has personal jurisdiction over Sun because Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc, and Sun Pharma Global FZE 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.*, Sun's Answer at ¶ 16, *Pfizer Inc., et al. v. Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries Inc.*, Case No. 21-285-CFC (D. Del. Mar. 33, 2021) (stating Sun did not contest personal jurisdiction for purposes of that specific action); Sun's Answer at 10–11, *Galderma Labs. L.P., et al. v. Sun Pharmaceutical Industries Ltd. et al.*, Case No. 18-1588-LPS (D. Del. Jan. 31, 2019) (asserting counterclaims); Complaint at 10–12, *Sun Pharma Global FZE and Sun Pharmaceutical Industries, Ltd. v. Teva Pharmaceuticals USA, Inc. et al*, Case No. 18-1552-RGA (D. Del. Oct. 9, 2018) (asserting claims); Sun's Answer at ¶ 12, *Pfizer Inc., et al. v. Micro Labs USA Inc., et al.*, Case No. 17-158-LPS (D. Del. July 11, 2018) (stating Sun did not contest personal jurisdiction for purposes of that specific action).

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

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

22. Alternatively, if Sun Pharmaceutical Industries Ltd.'s and/or Sun Pharma Global FZE's connections with Delaware, including their connections with Sun Pharmaceutical Industries, Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Sun Pharmaceutical Industries Ltd. and/or Sun Pharma Global FZE are not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Sun Pharmaceutical Industries Ltd. and/or Sun Pharma Global FZE in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

VENUE

23. Venue is proper in this district as to Sun Pharmaceutical Industries, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharmaceutical Industries, 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.

24. Venue is proper in this district as to Sun Pharmaceutical Industries Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharmaceutical Industries 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.

25. Venue is proper in this district as to Sun Pharma Global FZE pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

26. XIIDRA®, which contains lifitegrast, is an ophthalmic solution indicated for the signs and symptoms of dry eye disease.

27. On information and belief, Sun's ANDA Product is a generic version of Novartis's XIIDRA®.

COUNT I – INFRINGEMENT OF THE '938 PATENT

28. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

29. The '938 patent, entitled "Modulators of Cellular Adhesion" (attached as Exhibit A), was duly and legally issued on January 1, 2008.

30. Novartis Pharmaceuticals Corporation is the owner and assignee of the '938 patent.

31. The '938 patent claims, *inter alia*, an isolated compound of the structure recited in claim 1, or a pharmaceutically acceptable salt, ester, salt, of such ester or prodrug thereof.

32. XIIDRA® is covered by one or more claims of the '938 patent, including claims 1 and 45 of the '938 patent, and the '938 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

33. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '938 patent.

34. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '938 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

35. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by at least claims 1 and 45 of the '938 patent.

36. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

37. In Sun's Third Notice Letter, Sun did not contest the infringement of claim 1 or claim 45 of the '938 patent on any basis other than the alleged invalidity of those claims.

38. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '938 patent was an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

39. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

40. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '938 patent, including, *inter alia*, claims 1 and 45 of the '938 patent.

41. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '938 patent, including, *inter alia*, claims 1 and 45 of the '938 patent.

42. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '938 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '938 patent and specific intent to infringe that patent.

43. Notwithstanding Sun's knowledge of the claims of the '938 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '938 patent.

44. The foregoing actions by Sun constitute and/or will constitute infringement of the '938 patent and active inducement of infringement by others of the '938 patent.

45. Novartis will be substantially and irreparably damaged by infringement of the '938 patent.

46. Unless Sun is enjoined from infringing the ’938 patent and actively inducing infringement of the ’938 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’938 PATENT

47. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

48. 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 Novartis on the one hand and Sun on the other regarding Sun’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’938 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the ’938 patent, will infringe and induce the infringement by others of the ’938 patent.

COUNT III – INFRINGEMENT OF THE ’460 PATENT

50. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

51. The ’460 patent, entitled, “Modulators of Cellular Adhesion” (attached as Exhibit B), was duly and legally issued on June 29, 2010.

52. Novartis Pharmaceuticals Corporation is the owner and assignee of the ’460 patent.

53. The ’460 patent claims, *inter alia,* a compound of the structure recited in claim 1, or pharmaceutically acceptable salts thereof.

54. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the ’460 patent, including claim 1 of the ’460 patent, and the ’460 patent has been listed in connection with XIIDRA® in the FDA’s Orange Book.

55. In Sun’s Notice Letters, Sun notified Novartis of the submission of Sun’s ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun’s ANDA Product prior to the expiration of the ’460 patent.

56. In Sun’s Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’460 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’460 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA Product.

57. On information and belief, Sun’s ANDA Product and the use of Sun’s ANDA Product are covered by at least claim 1 of the ’460 patent.

58. According to Sun’s Notice Letters, Sun’s ANDA Product contains lifitegrast.

59. In Sun’s Third Notice Letter, Sun did not contest the infringement of claim 1 of the ’460 patent on any basis other than the alleged invalidity of that claim.

60. Sun’s submission of Sun’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA

Product before the expiration of the ’460 patent was an act of infringement of the ’460 patent under 35 U.S.C. § 271(e)(2)(A).

61. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun’s ANDA Product immediately and imminently upon approval of its ANDA.

62. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’460 patent, including, *inter alia*, claim 1 of the ’460 patent.

63. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’460 patent, including, *inter alia,* claim 1 of the ’460 patent.

64. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’460 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’460 patent and specific intent to infringe that patent.

65. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’460 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’460 patent immediately and imminently upon approval of Sun’s ANDA.

66. Notwithstanding Sun's knowledge of the claims of the '460 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '460 patent.

67. The foregoing actions by Sun constitute and/or will constitute infringement of the '460 patent; active inducement of infringement of the '460 patent; and contribution to the infringement by others of the '460 patent.

68. Novartis will be substantially and irreparably damaged by infringement of the '460 patent.

69. Unless Sun is enjoined from infringing the '460 patent, actively inducing infringement of the '460 patent, and contributing to the infringement by others of the '460 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '460 PATENT

70. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

71. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '460 patent.

72. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '460 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '460 patent.

COUNT V – INFRINGEMENT OF THE '743 PATENT

73. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

74. The '743 patent, entitled "Modulators of Cellular Adhesion" (attached as Exhibit C), was duly and legally issued on September 7, 2010.

75. Novartis Pharmaceuticals Corporation is the owner and assignee of the '743 patent.

76. Claim 24 of the '743 patent is directed to a method of inhibiting an interaction between a CD11a/CD18 leukointegrin and a member of the ICAM family of cellular adhesion molecules comprising administering to a cell an effective amount of a compound that is a competitive inhibitor of said CD11/CD18-ICAM interaction whereby said ligand/receptor interaction between said integrin and said intercellular adhesion molecule is decreased, and wherein said compound comprises a compound of Formula I or a pharmaceutically acceptable salt thereof wherein the R^{4A} and R^{4B} are independently a halogen which is F, Cl, Br, or I.

77. Claim 46 of the '743 patent is directed to a method of inhibiting an interaction between a CD11a/CD18 leukointegrin and a member of the ICAM family of cellular adhesion molecules comprising administering to a cell an effective amount of a compound that is a competitive inhibitor of said CD11/CD18-ICAM interaction whereby said ligand/receptor interaction between said integrin and said intercellular adhesion molecule is decreased, and wherein the compound of Formula I is a compound wherein AR^1 has one of the structures recited in claim 46.

78. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '743 patent, including claims 24 and 46, of the '743 patent, and the '743 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

79. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '743 patent.

80. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '743 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '743 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

81. On information and belief, the use according to the proposed labeling of Sun's ANDA Product is covered by at least claims 24 and 46 of the '743 patent.

82. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

83. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

84. On information and belief, the proposed labeling for Sun's ANDA Product provides that lifitegrast is a lymphocyte function-associated antigen-1 (LFA-1) antagonist.

85. According to Sun's Notice Letters, the strength for Sun's ANDA Product is 5%.

86. On information and belief, the proposed labeling for Sun's ANDA Product provides that Sun's ANDA Product is indicated for the treatment of the signs and symptoms of dry eye disease. On information and belief, the proposed labeling for Sun's ANDA Product directs,

encourages, and induces the use of Sun's ANDA Product in a method that infringes claims 24 and 46 of the '743 patent.

87. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the administration of one drop twice daily in each eye of Sun's ANDA Product.

88. In Sun's third Notice Letter, Sun did not contest the infringement of claims 24 or 46 of the '743 patent on any basis other than the alleged invalidity of those claims.

89. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '743 patent was an act of infringement of the '743 patent under 35 U.S.C. § 271(e)(2)(A).

90. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

91. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '743 patent, including, *inter alia*, claims 24 and 46 of the '743 patent.

92. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '743 patent, including, *inter alia*, claims 24 and 46 of the '743 patent.

93. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '743 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '743 patent and specific intent to infringe that patent.

94. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '743 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '743 patent immediately and imminently upon approval of Sun's ANDA.

95. Notwithstanding Sun's knowledge of the claims of the '743 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '743 patent.

96. The foregoing actions by Sun constitute and/or will constitute infringement of the '743 patent; active inducement of infringement of the '743 patent; and contribution to the infringement by others of the '743 patent.

97. Novartis will be substantially and irreparably damaged by infringement of the '743 patent.

98. Unless Sun is enjoined from infringing the '743 patent, actively inducing infringement of the '743 patent, and contributing to the infringement by others of the '743 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '743 PATENT

99. Novartis incorporates each of the proceeding 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '743 patent.

101. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '743 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '743 patent.

COUNT VII – INFRINGEMENT OF THE '122 PATENT

102. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

103. The '122 patent, entitled, "Modulators of Cellular Adhesion" (attached as Exhibit D), was duly and legally issued on April 19, 2011.

104. Novartis Pharmaceuticals Corporation is the owner and assignee of the '122 patent.

105. The '122 patent claims, *inter alia*, a compound of the structure recited in claim 7, or pharmaceutically acceptable salts thereof.

106. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '122 patent, including claim 7 of the '122 patent, and the '122 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

107. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in

the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '122 patent.

108. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '122 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '122 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

109. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by at least claim 7 of the '122 patent.

110. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast, a compound that is covered by at least claim 7 of the '122 patent.

111. In Sun's Third Notice Letter, Sun did not contest the infringement of claim 7 of the '122 patent on any basis other than the alleged invalidity of that claim.

112. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '122 patent was an act of infringement of the '122 patent under 35 U.S.C. § 271(e)(2)(A).

113. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

114. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '122 patent, including, *inter alia*, claim 7 of the '122 patent.

115. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '122 patent, including, *inter alia*, claim 7 of the '122 patent.

116. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '122 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '122 patent and specific intent to infringe that patent.

117. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '122 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '122 patent immediately and imminently upon approval of Sun's ANDA.

118. Notwithstanding Sun's knowledge of the claims of the '122 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '122 patent.

119. The foregoing actions by Sun constitute and/or will constitute infringement of the '122 patent; active inducement of infringement of the '122 patent; and contribution to the infringement by others of the '122 patent.

120. Novartis will be substantially and irreparably damaged by infringement of the '122 patent.

121. Unless Sun is enjoined from infringing the '122 patent, actively inducing infringement of the '122 patent, and contributing to the infringement by others of the '122 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '122 PATENT

122. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

123. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '122 patent.

124. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '122 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '122 patent.

COUNT IX – INFRINGEMENT OF THE '174 PATENT

125. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

126. The '174 patent, entitled, "Modulators of Cellular Adhesion" (attached as Exhibit E), was duly and legally issued on December 22, 2015.

127. Novartis Pharmaceuticals Corporation is the owner and assignee of the '174 patent.

128. The '174 patent claims, *inter alia*, a pharmaceutical formulation comprising an LFA-1 antagonist, wherein the formulation is for topical administration and wherein the LFA-1 antagonist comprises a compound of Formula I, or its pharmaceutically acceptable salt or ester, with the structure recited in claim 1 of the '174 patent.

129. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '174 patent, including claim 1 of the '174 patent, and the '174 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

130. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '174 patent.

131. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '174 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '174 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

132. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by at least claim 1 of the '174 patent.

133. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

134. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

135. On information and belief, the proposed labeling for Sun's ANDA Product provides that lifitegrast is a lymphocyte function-associated antigen-1 (LFA-1) antagonist.

136. On information and belief, Sun's ANDA Product contains an excipient.

137. In Sun's Third Notice Letter, Sun did not contest the infringement of claim 1 of the '174 patent on any basis other than the alleged invalidity of that claim.

138. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '174 patent was an act of infringement of the '174 patent under 35 U.S.C. § 271(e)(2)(A).

139. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

140. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '174 patent, including, *inter alia*, claim 1 of the '174 patent.

141. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '174 patent, including, *inter alia*, claim 1 of the '174 patent.

142. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '174 patent when Sun's ANDA is approved, and plans and intends to, and will,

do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '174 patent and specific intent to infringe that patent.

143. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '174 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '174 patent immediately and imminently upon approval of Sun's ANDA.

144. Notwithstanding Sun's knowledge of the claims of the '174 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '174 patent.

145. The foregoing actions by Sun constitute and/or will constitute infringement of the '174 patent; active inducement of infringement of the '174 patent; and contribution to the infringement by others of the '174 patent.

146. Novartis will be substantially and irreparably damaged by infringement of the '174 patent.

147. Unless Sun is enjoined from infringing the '174 patent, actively inducing infringement of the '174 patent, and contributing to the infringement by others of the '174 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '174 PATENT

148. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

149. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '174 patent.

150. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '174 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '174 patent.

COUNT XI – INFRINGEMENT OF THE '000 PATENT

151. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

152. The '000 patent, entitled, "Modulators of Cellular Adhesion" (attached as Exhibit F), was duly and legally issued on November 13, 2018.

153. Novartis Pharmaceuticals Corporation is the owner and assignee of the '000 patent.

154. The '000 patent claims, *inter alia*, a method for treatment of an inflammatory or immune related disorder in a subject comprising topically administering to said subject in need thereof a formulation comprising an LFA-1 antagonist and a pharmaceutically acceptable excipient, wherein the LFA-1 antagonist comprises a compound of Formula I, or its pharmaceutically acceptable salt or ester, with the structure recited in claim 1 of the '000 patent.

155. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '000 patent, including claim 1 of the '000 patent, and the '000 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

156. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '000 patent.

157. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '000 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '000 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

158. On information and belief, the use of Sun's ANDA Product is covered by at least claim 1 of the '000 patent.

159. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

160. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

161. On information and belief, the proposed labeling for Sun's ANDA Product provides that lifitegrast is a lymphocyte function-associated antigen-1 (LFA-1) antagonist.

162. On information and belief, the proposed labeling for Sun's ANDA Product provides that Sun's ANDA Product is indicated for the treatment of the signs and symptoms of dry eye disease. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the use of Sun's ANDA Product in a method that infringes claim 1 of the '000 patent.

163. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the administration of one drop twice daily in each eye of Sun's ANDA Product.

164. On information and belief, Sun's ANDA Product contains a pharmaceutically acceptable excipient.

165. In Sun's Third Notice Letter, Sun did not contest the infringement of claim 1 of the '000 patent on any basis other than the alleged invalidity of that claim.

166. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '000 patent was an act of infringement of the '000 patent under 35 U.S.C. § 271(e)(2)(A).

167. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

168. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '000 patent, including, *inter alia*, claim 1 of the '000 patent.

169. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '000 patent, including, *inter alia*, claim 1 of the '000 patent.

170. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’000 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’000 patent and specific intent to infringe that patent.

171. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’000 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’000 patent immediately and imminently upon approval of Sun’s ANDA.

172. Notwithstanding Sun’s knowledge of the claims of the ’000 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun’s ANDA Product with its product labeling following FDA approval of Sun’s ANDA prior to the expiration of the ’000 patent.

173. The foregoing actions by Sun constitute and/or will constitute infringement of the ’000 patent; active inducement of infringement of the ’000 patent; and contribution to the infringement by others of the ’000 patent.

174. Novartis will be substantially and irreparably damaged by infringement of the ’000 patent.

175. Unless Sun is enjoined from infringing the ’000 patent, actively inducing infringement of the ’000 patent, and contributing to the infringement by others of the ’000 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '000 PATENT

176. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

177. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '000 patent.

178. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '000 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '000 patent.

COUNT XIII – INFRINGEMENT OF THE '047 PATENT

179. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

180. The '047 patent, entitled "Compositions and Methods for Treatment of Eye Disorders" (attached as Exhibit G), was duly and legally issued on December 27, 2011.

181. Novartis Pharmaceuticals Corporation is the owner and assignee of the '047 patent.

182. The '047 patent claims, *inter alia*, a compound with the formula recited in claim 1, or a pharmaceutically acceptable salt thereof.

183. The '047 patent claims, *inter alia*, in claim 2, a composition comprising an effective amount of a compound with the formula recited in claim 1 and a pharmaceutically acceptable vehicle.

184. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the ’047 patent, including claims 1 and 2 of the ’047 patent, and the ’047 patent has been listed in connection with XIIDRA® in the FDA’s Orange Book.

185. In Sun’s Notice Letters, Sun notified Novartis of the submission of Sun’s ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun’s ANDA Product prior to the expiration of the ’047 patent.

186. In Sun’s Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’047 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’047 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA Product.

187. On information and belief, Sun’s ANDA Product and the use of Sun’s ANDA Product are covered by at least claims 1 and 2 of the ’047 patent.

188. According to Sun’s Notice Letters, Sun’s ANDA Product, a pharmaceutical composition, contains lifitegrast.

189. In Sun’s Third Notice Letter, Sun did not contest the infringement of claim 1 or 2 of the ’047 patent on any basis other than the alleged invalidity of those claims.

190. Sun’s submission of Sun’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA

Product before the expiration of the ’047 patent was an act of infringement of the ’047 patent under 35 U.S.C. § 271(e)(2)(A).

191. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun’s ANDA Product immediately and imminently upon approval of its ANDA.

192. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’047 patent, including, *inter alia*, claims 1 and 2 of the ’047 patent.

193. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’047 patent, including, *inter alia*, claims 1 and 2 of the ’047 patent.

194. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’047 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’047 patent and specific intent to infringe that patent.

195. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’047 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’047 patent immediately and imminently upon approval of Sun’s ANDA.

196. Notwithstanding Sun's knowledge of the claims of the '047 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '047 patent.

197. The foregoing actions by Sun constitute and/or will constitute infringement of the '047 patent; active inducement of infringement of the '047 patent; and contribution to the infringement by others of the '047 patent.

198. Novartis will be substantially and irreparably damaged by infringement of the '047 patent.

199. Unless Sun is enjoined from infringing the '047 patent, actively inducing infringement of the '047 patent, and contributing to the infringement by others of the '047 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XIV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '047 PATENT

200. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

201. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '047 patent.

202. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '047 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '047 patent.

COUNT XV – INFRINGEMENT OF THE '655 PATENT

203. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

204. The '655 patent, entitled "Compositions and Methods for Treatment of Eye Disorders" (attached as Exhibit H), was duly and legally issued on May 1, 2012.

205. Novartis Pharmaceuticals Corporation is the owner and assignee of the '655 patent.

206. The '655 patent claims, *inter alia*, a method of treating dry eye disease in a subject without Sjogren's syndrome by administering to said subject an effective amount of an LFA-1 antagonist or its pharmaceutically acceptable salts or esters, wherein said LFA-1 antagonist has the structure recited in claim 1 of the '655 patent.

207. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '655 patent, including claims 1 and 2 of the '655 patent, and the '655 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

208. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '655 patent.

209. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '655 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '655 patent is invalid, unenforceable, and/or

will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

210. On information and belief, the use of Sun's ANDA Product is covered by at least claims 1 and 2 of the '655 patent.

211. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

212. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

213. On information and belief, the proposed labeling for Sun's ANDA Product provides that lifitegrast is a lymphocyte function-associated antigen-1 (LFA-1) antagonist.

214. On information and belief, the proposed labeling for Sun's ANDA Product provides that Sun's ANDA Product is indicated for the treatment of the signs and symptoms of dry eye disease. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the use of Sun's ANDA Product in a method that infringes claims 1 and 2 of the '655 patent.

215. According to Sun's Notice Letters, the strength for Sun's ANDA Product is 5%.

216. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the administration of one drop twice daily in each eye of Sun's ANDA Product.

217. In Sun's Third Notice Letter, Sun did not contest the infringement of claims 1 and 2 of the '655 patent on any basis other than the alleged invalidity of those claims.

218. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA

Product before the expiration of the ’655 patent was an act of infringement of the ’655 patent under 35 U.S.C. § 271(e)(2)(A).

219. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun’s ANDA Product immediately and imminently upon approval of its ANDA.

220. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’655 patent, including, *inter alia*, claims 1 and 2 of the ’655 patent.

221. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’655 patent, including, *inter alia*, claims 1 and 2 of the ’655 patent.

222. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’655 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’655 patent and specific intent to infringe that patent.

223. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’655 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’655 patent immediately and imminently upon approval of Sun’s ANDA.

224. Notwithstanding Sun's knowledge of the claims of the '655 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '655 patent.

225. The foregoing actions by Sun constitute and/or will constitute infringement of the '655 patent; active inducement of infringement of the '655 patent; and contribution to the infringement by others of the '655 patent.

226. Novartis will be substantially and irreparably damaged by infringement of the '655 patent.

227. Unless Sun is enjoined from infringing the '655 patent, actively inducing infringement of the '655 patent, and contributing to the infringement by others of the '655 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XVI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '655 PATENT

228. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

229. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '655 patent.

230. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '655 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '655 patent.

COUNT XVII – INFRINGEMENT OF THE '450 PATENT

231. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

232. The '450 patent, entitled "Compositions and Methods for Treatment of Eye Disorders" (attached as Exhibit I), was duly and legally issued on November 26, 2013.

233. Novartis Pharmaceuticals Corporation is the owner and assignee of the '450 patent.

234. The '450 patent claims, *inter alia*, a method of treating dry eye disease in a subject with Sjogren's syndrome by administering to said subject an effective amount of a lymphocyte function associated antigen-1 (LFA-1) antagonist or a pharmaceutically acceptable salt or ester thereof, wherein the LFA-1 antagonist has the structure recited in claim 1 of the '450 patent.

235. Claim 20 of the '450 patent is directed to a method of treating dry eye disorder in a subject in need thereof comprising administering to an eye of a subject an effective amount of a pharmaceutical composition comprising an LFA-1 antagonist and/or its pharmaceutically acceptable salts or esters, wherein said LFA-1 antagonist has the structure recited in claim 20 and wherein said subject has Sjogren's syndrome, and wherein said administering comprises administering said compound in liquid drops.

236. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '450 patent, including claims 1 and 20 of the '450 patent, and the '450 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

237. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '450 patent.

238. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '450 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '450 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

239. On information and belief, the use of Sun's ANDA Product is covered by at least claims 1 and 20 of the '450 patent.

240. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

241. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

242. On information and belief, the proposed labeling for Sun's ANDA Product provides that lifitegrast is a lymphocyte function-associated antigen-1 (LFA-1) antagonist.

243. On information and belief, the proposed labeling for Sun's ANDA Product provides that Sun's ANDA Product is indicated for the treatment of the signs and symptoms of dry eye disease. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the use of Sun's ANDA Product in a method that infringes claims 1 and 20 of the '450 patent.

244. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the administration of one drop twice daily in each eye of Sun's ANDA Product.

245. According to Sun's Notice Letters, the strength for Sun's ANDA Product is 5%.

246. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the administration of one drop twice daily in each eye of Sun's ANDA Product.

247. In Sun's Third Notice Letter, Sun did not contest the infringement of claims 1 and 20 of the '450 patent on any basis other than the alleged invalidity of those claims.

248. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '450 patent was an act of infringement of the '450 patent under 35 U.S.C. § 271(e)(2)(A).

249. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

250. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '450 patent, including, *inter alia*, claims 1 and 20 of the '450 patent.

251. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '450 patent, including, *inter alia*, claims 1 and 20 of the '450 patent.

252. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '450 patent when Sun's ANDA is approved, and plans and intends to, and will,

do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '450 patent and specific intent to infringe that patent.

253. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '450 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '450 patent immediately and imminently upon approval of Sun's ANDA.

254. Notwithstanding Sun's knowledge of the claims of the '450 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '450 patent.

255. The foregoing actions by Sun constitute and/or will constitute infringement of the '450 patent; active inducement of infringement of the '450 patent; and contribution to the infringement by others of the '450 patent.

256. Novartis will be substantially and irreparably damaged by infringement of the '450 patent.

257. Unless Sun is enjoined from infringing the '450 patent, actively inducing infringement of the '450 patent, and contributing to the infringement by others of the '450 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XVIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '450 PATENT

258. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

259. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '450 patent.

260. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '450 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '450 patent.

COUNT XIX – INFRINGEMENT OF THE '701 PATENT

261. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

262. The '701 patent, entitled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof" (attached as Exhibit J), was duly and legally issued on February 5, 2013.

263. Novartis Pharmaceuticals Corporation is the owner and assignee of the '701 patent.

264. The '701 patent claims, *inter alia,* in claim 2, a composition comprising a compound of Formula I with the structure recited in claim 1 comprising a purity of greater than about 98%, and/or a pharmaceutically acceptable salt thereof.

265. The '701 patent claims, *inter alia,* in claim 3, a composition comprising a compound of Formula I with the structure recited in claim 1 wherein the compound comprises at least about 95% of an S-enantiomer.

266. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '701 patent, including claims 2 and 3 of the '701 patent, and the '701 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

267. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '701 patent.

268. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '701 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '701 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

269. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by at least claims 2 and 3 of the '701 patent.

270. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

271. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

272. On information and belief, Sun's ANDA Product satisfies the purity limitation of claim 2.

273. In Sun's Third Notice Letter, Sun did not contest the infringement of claims 2 or 3 of the '701 patent on any basis other than the alleged invalidity of those claims.

274. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA

Product before the expiration of the ’701 patent was an act of infringement of the ’701 patent under 35 U.S.C. § 271(e)(2)(A).

275. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun’s ANDA Product immediately and imminently upon approval of its ANDA.

276. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’701 patent, including, *inter alia*, claims 2 and 3 of the ’701 patent.

277. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’701 patent, including, *inter alia*, claims 2 and 3 of the ’701 patent.

278. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’701 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’701 patent and specific intent to infringe that patent.

279. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’701 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’701 patent immediately and imminently upon approval of Sun’s ANDA.

280. Notwithstanding Sun's knowledge of the claims of the '701 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '701 patent.

281. The foregoing actions by Sun constitute and/or will constitute infringement of the '701 patent; active inducement of infringement of the '701 patent; and contribution to the infringement by others of the '701 patent.

282. Novartis will be substantially and irreparably damaged by infringement of the '701 patent.

283. Unless Sun is enjoined from infringing the '701 patent, actively inducing infringement of the '701 patent, and contributing to the infringement by others of the '701 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XX – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '701 PATENT

284. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

285. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '701 patent.

286. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '701 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '701 patent.

COUNT XXI – INFRINGEMENT OF THE '077 PATENT

287. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

288. The '077 patent, entitled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof" (attached as Exhibit K), was duly and legally issued on September 20, 2016.

289. Novartis Pharmaceuticals Corporation is the owner and assignee of the '077 patent.

290. The '077 patent claims, *inter alia,* in claim 2, a method of treating dry eye disease in a subject in need of such treatment, the method comprising administering to the subject an effective amount of a composition comprising an isolated compound of Formula I with the structure recited in claim 1, or a pharmaceutically acceptable salt thereof, wherein said compound comprises a purity of greater than about 98%.

291. The '077 patent claims, *inter alia,* in claim 3, a method of treating dry eye disease in a subject in need of such treatment, the method comprising administering to the subject an effective amount of a composition comprising an isolated compound of Formula I with the structure recited in claim 1, or a pharmaceutically acceptable salt thereof, wherein said compound comprises at least about 95% of an S-enantiomer.

292. XIIDRA®, as well as methods of using XIIDRA®, are covered by one or more claims of the '077 patent, including claims 2 and 3 of the '077 patent, and the '077 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

293. In Sun's Notice Letters, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '077 patent.

294. In Sun's Third Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '077 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

295. On information and belief, the use of Sun's ANDA Product is covered by at least claims 2 and 3 of the '077 patent.

296. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

297. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

298. On information and belief, the proposed labeling for Sun's ANDA Product provides that Sun's ANDA Product is indicated for the treatment of the signs and symptoms of dry eye disease. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the use of Sun's ANDA Product in a method that infringes claims 2 and 3 of the '077 patent.

299. According to Sun's Notice Letters, the strength for Sun's ANDA Product is 5%.

300. On information and belief, the proposed labeling for Sun's ANDA Product directs, encourages, and induces the administration of one drop twice daily in each eye of Sun's ANDA Product.

301. On information and belief, Sun's ANDA Product satisfies the purity limitation of claim 1.

302. In Sun's Third Notice Letter, Sun did not contest the infringement of claims 2 or 3 of the '077 patent on any basis other than the alleged invalidity of those claims.

303. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '077 patent was an act of infringement of the '077 patent under 35 U.S.C. § 271(e)(2)(A).

304. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

305. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '077 patent, including, *inter alia*, claims 2 and 3 of the '077 patent.

306. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '077 patent, including, *inter alia*, claims 2 and 3 of the '077 patent.

307. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '077 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '077 patent and specific intent to infringe that patent.

308. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '077 patent, that Sun's ANDA

Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '077 patent immediately and imminently upon approval of Sun's ANDA.

309. Notwithstanding Sun's knowledge of the claims of the '077 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '077 patent.

310. The foregoing actions by Sun constitute and/or will constitute infringement of the '077 patent; active inducement of infringement of the '077 patent; and contribution to the infringement by others of the '077 patent.

311. Novartis will be substantially and irreparably damaged by infringement of the '077 patent.

312. Unless Sun is enjoined from infringing the '077 patent, actively inducing infringement of the '077 patent, and contributing to the infringement by others of the '077 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XXII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '077 PATENT

313. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

314. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '077 patent.

315. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '077 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '077 patent.

COUNT XXIII – INFRINGEMENT OF THE '574 PATENT

316. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

317. The '574 patent, entitled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof" (attached as Exhibit L), was duly and legally issued on January 6, 2015.

318. Novartis Pharmaceuticals Corporation is the owner and assignee of the '574 patent.

319. The '574 patent claims, *inter alia*, a composition comprising an isolated compound of Formula I with the structure recited in claim 1, or a salt thereof, wherein said compound is synthesized according to a method comprising the steps recited in claim 1 of the '574 patent.

320. XIIDRA® is covered by one or more claims of the '574 patent, including claim 1 of the '574 patent, and the '574 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

321. In Sun's First Notice Letter, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '574 patent.

322. In Sun's First Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '574 patent. On information and belief, Sun

submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '574 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

323. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by at least claim 1 of the '574 patent.

324. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

325. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

326. On information and belief, the lifitegrast in Sun's ANDA Product is synthesized according to the steps recited in claim 1 of the '574 patent.

327. On information and belief, Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '574 patent was an act of infringement of the '574 patent under 35 U.S.C. § 271(e)(2)(A).

328. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

329. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '574 patent, including, *inter alia*, claim 1 of the '574 patent.

330. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling

would infringe one or more claims of the ’574 patent, including, *inter alia*, claim 1 of the ’574 patent.

331. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’574 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’574 patent and specific intent to infringe that patent.

332. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’574 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’574 patent immediately and imminently upon approval of Sun’s ANDA.

333. Notwithstanding Sun’s knowledge of the claims of the ’574 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun’s ANDA Product with its product labeling following FDA approval of Sun’s ANDA prior to the expiration of the ’574 patent.

334. The foregoing actions by Sun constitute and/or will constitute infringement of the ’574 patent; active inducement of infringement of the ’574 patent; and contribution to the infringement by others of the ’574 patent.

335. Novartis will be substantially and irreparably damaged by infringement of the ’574 patent.

336. Unless Sun is enjoined from infringing the ’574 patent and/or actively inducing infringement of the ’574 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XXIV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’574 PATENT

337. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

338. 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 Novartis on the one hand and Sun on the other regarding Sun’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’574 patent.

339. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the ’574 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’574 patent.

COUNT XXV – INFRINGEMENT OF THE ’088 PATENT

340. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

341. The ’088 patent, entitled “Crystalline Pharmaceutical and Methods of Preparation and Use Thereof” (attached as Exhibit M), was duly and legally issued on May 31, 2016.

342. Novartis Pharmaceuticals Corporation is the owner and assignee of the ’088 patent.

343. The ’088 patent claims, *inter alia*, a composition comprising an isolated compound of Formula I with the structure recited in claim 1 wherein said compound is synthesized according to a method comprising the steps recited in claim 1 of the ’088 patent.

344. XIIDRA® is covered by one or more claims of the ’088 patent, including claim 1 of the ’088 patent, and the ’088 patent has been listed in connection with XIIDRA® in the FDA’s Orange Book.

345. In Sun’s First Notice Letter, Sun notified Novartis of the submission of Sun’s ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun’s ANDA Product prior to the expiration of the ’088 patent.

346. In Sun’s First Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’088 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’088 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA Product.

347. On information and belief, Sun’s ANDA Product and the use of Sun’s ANDA Product are covered by at least claim 1 of the ’088 patent.

348. According to Sun’s Notice Letters, Sun’s ANDA Product is an ophthalmic solution.

349. According to Sun’s Notice Letters, Sun’s ANDA Product contains lifitegrast.

350. On information and belief, the lifitegrast in Sun’s ANDA Product is synthesized according to the steps recited in claim 1 of the ’088 patent.

351. In Sun’s First Notice Letter, Sun did not contest the infringement of claim 1 of the ’088 patent on any basis other than the alleged invalidity of that claim.

352. On information and belief, Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '088 patent was an act of infringement of the '088 patent under 35 U.S.C. § 271(e)(2)(A).

353. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

354. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '088 patent, including, *inter alia*, claim 1 of the '088 patent.

355. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '088 patent, including, *inter alia*, claim 1 of the '088 patent.

356. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '088 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '088 patent and specific intent to infringe that patent.

357. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '088 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief,

Sun plans and intends to, and will, contribute to infringement of the ’088 patent immediately and imminently upon approval of Sun’s ANDA.

358. Notwithstanding Sun’s knowledge of the claims of the ’088 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun’s ANDA Product with its product labeling following FDA approval of Sun’s ANDA prior to the expiration of the ’088 patent.

359. The foregoing actions by Sun constitute and/or will constitute infringement of the ’088 patent; active inducement of infringement of the ’088 patent; and contribution to the infringement by others of the ’088 patent.

360. Novartis will be substantially and irreparably damaged by infringement of the ’088 patent.

361. Unless Sun is enjoined from infringing the ’088 patent and/or actively inducing infringement of the ’088 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XXVI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’088 PATENT

362. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

363. 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 Novartis on the one hand and Sun on the other regarding Sun’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’088 patent.

364. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product with its proposed labeling, or any other Sun drug product

that is covered by or whose use is covered by the ’088 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’088 patent.

COUNT XXVII – INFRINGEMENT OF THE ’141 PATENT

365. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

366. The ’141 patent, entitled “Crystalline Pharmaceutical and Methods of Preparation and Use Thereof” (attached as Exhibit N), was duly and legally issued on February 13, 2018.

367. Novartis Pharmaceuticals Corporation is the owner and assignee of the ’141 patent.

368. The ’141 patent claims, *inter alia*, a composition comprising an isolated compound of Formula I with the structure recited in claim 1 wherein said compound is synthesized according to a method comprising the steps recited in claim 1 of the ’141 patent.

369. XIIDRA® is covered by one or more claims of the ’141 patent, including claim 1 of the ’141 patent, and the ’141 patent has been listed in connection with XIIDRA® in the FDA’s Orange Book.

370. In Sun’s First Notice Letter, Sun notified Novartis of the submission of Sun’s ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun’s ANDA Product prior to the expiration of the ’141 patent.

371. In Sun’s First Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’141 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’141 patent is invalid, unenforceable, and/or

will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

372. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by at least claim 1 of the '141 patent.

373. According to Sun Notice Letters, Sun's ANDA Product is an ophthalmic solution.

374. According to Sun Notice Letters, Sun's ANDA Product contains lifitegrast.

375. On information and belief, the lifitegrast in Sun's ANDA Product is synthesized according to the steps recited in claim 1 of the '141 patent.

376. On information and belief, Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '141 patent was an act of infringement of the '141 patent under 35 U.S.C. § 271(e)(2)(A).

377. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

378. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '141 patent, including, *inter alia*, claim 1 of the '141 patent.

379. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '141 patent, including, *inter alia,* claim 1 of the '141 patent.

380. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '141 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '141 patent and specific intent to infringe that patent.

381. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '141 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '141 patent immediately and imminently upon approval of Sun's ANDA.

382. Notwithstanding Sun's knowledge of the claims of the '141 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '141 patent.

383. The foregoing actions by Sun constitute and/or will constitute infringement of the '141 patent; active inducement of infringement of the '141 patent; and contribution to the infringement by others of the '141 patent.

384. Novartis will be substantially and irreparably damaged by infringement of the '141 patent.

385. Unless Sun is enjoined from infringing the '141 patent and/or actively inducing infringement of the '141 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XXVIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '141 PATENT

386. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

387. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '141 patent.

388. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '141 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '141 patent.

COUNT XXIX – INFRINGEMENT OF THE '553 PATENT

389. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

390. The '553 patent, entitled "LFA-1 Inhibitor and Methods of Preparation and Polymorph Thereof" (attached as Exhibit O), was duly and legally issued on July 21, 2015.

391. Novartis Pharmaceuticals Corporation is the owner and assignee of the '553 patent.

392. The '553 patent claims, *inter alia*, a composition comprising a compound of Formula I with the structure recited in claim 16, wherein said compound is synthesized according to a method comprising the steps recited in claim 16 of the '553 patent.

393. XIIDRA® is covered by one or more claims of the '553 patent, including claim 16 of the '553 patent, and the '553 patent has been listed in connection with XIIDRA® in the FDA's Orange Book.

394. In Sun's First Notice Letter, Sun notified Novartis of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's ANDA Product prior to the expiration of the '553 patent.

395. In Sun's First Notice Letter, Sun also notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '553 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '553 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

396. On information and belief, Sun's ANDA Product is covered by at least claim 16 of the '553 patent.

397. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

398. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

399. On information and belief, the lifitegrast in Sun's ANDA Product is synthesized according to the steps recited in claim 16 of the '553 patent.

400. On information and belief, Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '553 patent was an act of infringement of the '553 patent under 35 U.S.C. § 271(e)(2)(A).

401. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

402. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '553 patent, including, *inter alia*, claim 16 of the '553 patent.

403. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '553 patent, including, *inter alia*, claim 16 of the '553 patent.

404. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '553 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '553 patent and specific intent to infringe that patent.

405. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '553 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '553 patent immediately and imminently upon approval of Sun's ANDA.

406. Notwithstanding Sun's knowledge of the claims of the '553 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's

ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '553 patent.

407. The foregoing actions by Sun constitute and/or will constitute infringement of the '553 patent; active inducement of infringement of the '553 patent; and contribution to the infringement by others of the '553 patent.

408. Novartis will be substantially and irreparably damaged by infringement of the '553 patent.

409. Unless Sun is enjoined from infringing the '553 patent and/or actively inducing infringement of the '553 patent, Sun will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XXX – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '553 PATENT

410. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

411. 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 Novartis on the one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '553 patent.

412. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '553 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '553 patent.

COUNT XXXI – INFRINGEMENT OF THE '677 PATENT

413. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

414. The ’677 patent, entitled “LFA-1 Inhibitor Formulations” (attached as Exhibit P), was duly and legally issued on July 13, 2021.

415. Novartis Pharmaceuticals Corporation is the owner and assignee of the ’677 patent.

416. The ’677 patent claims, *inter alia*, a composition comprising a compound of Formula I with the structure recited in claim 13, and 0.2 to 0.4% antioxidant, the antioxidant being sodium thiosulfate, wherein the composition is an aqueous solution with the compound of Formula I dissolved therein, and wherein the composition is suitable for topical administration to the eye.

417. The ’677 patent claims, *inter alia*, a composition comprising a compound of Formula I with the structure recited in claim 14, and about 0.3% antioxidant, the antioxidant being sodium thiosulfate, as well as other excipients, wherein the composition is an aqueous solution with the compound of Formula I dissolved therein, and wherein the composition is suitable for topical administration to the eye.

418. XIIDRA® is covered by one or more claims of the ’677 patent, including claims 13 and 14 of the ’677 patent, and the ’677 patent has been listed in connection with XIIDRA® in the FDA’s Orange Book.

419. In Sun’s Second Notice Letter, Sun notified Novartis that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’677 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’677 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA Product, and seeking approval from the FDA to market Sun’s ANDA Product prior to the expiration of the ’677 patent.

420. On information and belief, Sun's ANDA Product is covered by at least claims 13 and 14 of the '677 patent.

421. According to Sun's Notice Letters, Sun's ANDA Product is an ophthalmic solution.

422. According to Sun's Notice Letters, Sun's ANDA Product contains lifitegrast.

423. On information and belief, Sun's ANDA Product comprises lifitegrast and 0.2 to 0.4% antioxidant, the antioxidant being sodium thiosulfate.

424. Sun's ANDA Product is an aqueous solution with lifitegrast dissolved therein.

425. Sun's ANDA Product is suitable for topical administration to the eye.

426. In Sun's Second Notice Letter, Sun did not contest the infringement of claims 13 or 14 of the '677 patent on any basis other than the alleged invalidity of that claim.

427. On information and belief, Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '677 patent was an act of infringement of the '677 patent under 35 U.S.C. § 271(e)(2)(A).

428. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

429. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '677 patent, including, *inter alia*, claims 13 and 14 of the '677 patent.

430. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling

would infringe one or more claims of the ’677 patent, including, *inter alia*, claims 13 and 14 of the ’677 patent.

431. On information and belief, Sun plans and intends to, and will, actively induce infringement of the ’677 patent when Sun’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun’s activities will be done with knowledge of the ’677 patent and specific intent to infringe that patent.

432. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’677 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the ’677 patent immediately and imminently upon approval of Sun’s ANDA.

433. Notwithstanding Sun’s knowledge of the claims of the ’677 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun’s ANDA Product with its product labeling following FDA approval of Sun’s ANDA prior to the expiration of the ’677 patent.

434. The foregoing actions by Sun constitute and/or will constitute infringement of the ’677 patent; active inducement of infringement of the ’677 patent; and contribution to the infringement by others of the ’677 patent.

435. Novartis will be substantially and irreparably damaged by infringement of the ’677 patent.

436. Unless Sun is enjoined from infringing the ’677 patent and/or actively inducing infringement of the ’677 patent, Sun will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT XXXII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’677 PATENT

437. Novartis incorporates each of the proceeding paragraphs as if fully set forth herein.

438. 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 Novartis on the one hand and Sun on the other regarding Sun’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’677 patent.

439. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the ’677 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’677 patent.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests 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 Sun’s submission to the FDA of Sun’s ANDA;

b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sun’s ANDA Product, or any other drug product that infringes or the use of which infringes one or more of the Patents-in-Suit, be not earlier than the latest of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

c) A preliminary and permanent injunction enjoining Sun, and all persons acting in concert with Sun, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the Patents-in-Suit, prior to the expiration of said patents, 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 Sun's ANDA Product, or any other drug product which is covered by or whose use is covered by one-or-more of the Patents-in-Suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;

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; and

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

Dated: August 23, 2022

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