IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff,* v. APOTEX INC. and APOTEX CORP., *Defendants.*	Civil Action No. _____

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff") files this Complaint for patent infringement against Apotex Inc. and Apotex Corp. (collectively, "Apotex"), and by its attorneys, hereby alleges as follows:

2. 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 Apotex's submission of an Abbreviated 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 Mekinist® (trametinib dimethyl sulfoxide) tablets, 0.5 mg and 2 mg, prior to the expiration of U.S. Patent No. 8,580,304 ("the '304 patent"); U.S. Patent No. 9,155,706 ("the '706 patent"); U.S. Patent No. 9,271,941 ("the '941 patent"); and 9,399,021 ("the '021 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

3. Apotex notified Novartis by letter dated September 17, 2025 ("Apotex's Notice Letter") that it had submitted to the FDA ANDA No. 220471 ("Apotex's ANDA"), seeking

approval from the FDA to engage in the commercial manufacture, use and/or sale of trametinib tablets, 0.5 mg and 2 mg, ("Apotex's ANDA Product") prior to the expiration of the Patents-in-Suit.

PARTIES

4. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

5. 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 59 Route 10, East Hanover, New Jersey 07936. Novartis Pharmaceuticals Corporation is the holder of New Drug Application ("NDA") No. 204114 for the manufacture and sale of trametinib dimethyl sulfoxide tablets, 0.5 mg and 2 mg, which has been approved by the FDA.

6. On information and belief, Apotex Inc. is a company organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

7. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

8. On information and belief, Apotex Corp. is the U.S. subsidiary of Apotex Inc., acts at the direction, and for the benefit, of Apotex Inc., and is controlled and/or dominated by Apotex Inc. Alternatively, on information and belief, Apotex Corp. and Apotex Inc. act at the direction, and for the benefit, of a common corporate parent, and are controlled and/or dominated by said common corporate parent.

9. On information and belief, Apotex is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION

10. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

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

12. This Court has personal jurisdiction over Defendant Apotex Corp.

13. Apotex Corp. 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. Apotex Corp. 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 located at 800 North State Street Suite 304, Dover, Delaware 19901. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Apotex Corp., acting in concert with Apotex 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.

14. On information and belief, Apotex Corp. knows and intends that following any approval of Apotex's ANDA No. 220471, Apotex Corp. will, in concert with Apotex Inc., manufacture and import into the United States Apotex's ANDA Product and directly or indirectly market, sell, and distribute Apotex's ANDA Product throughout the United States, including in

Delaware. On information and belief, following any FDA approval of ANDA No. 220471, Apotex Corp. knows and intends that Apotex's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

15. Apotex Corp. has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. On information and belief, Apotex Corp., with knowledge of the Hatch-Waxman Act process, directed Apotex's Notice Letter to Novartis Pharmaceuticals Corporation, an entity incorporated in Delaware, and alleged in Apotex's Notice Letter that each claim of the Patents-in-Suit is invalid and/or not infringed. On information and belief, Apotex Corp. knowingly and deliberately challenged Novartis's patent rights, and knew when it did so that it was triggering the provisions of the Hatch-Waxman Act for Novartis to bring an action for patent infringement.

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

18. On information and belief, if Apotex's ANDA is approved, Apotex Corp. will directly or indirectly market, sell, and/or distribute Apotex's ANDA Product within the United

States, including in Delaware, consistent with Apotex Corp.'s practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Apotex Corp. 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, Apotex Corp.'s generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Apotex'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 the claims of the Patents-in-Suit in the event that Apotex's ANDA Product is approved before the patents expire.

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

20. This Court has personal jurisdiction over Defendant Apotex Inc.

21. Apotex 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. On information and belief, Apotex Inc., acting in concert with Apotex Corp., 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.

22. On information and belief, Apotex Inc. knows and intends that following any approval of Apotex's ANDA No. 220471, Apotex Inc. will, in concert with Apotex Corp., manufacture and import into the United States Apotex's ANDA Product and directly or indirectly market, sell, and distribute Apotex's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 220471, Apotex Inc. knows and intends that Apotex's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

23. Apotex Inc. 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.

24. On information and belief, Apotex Inc., with knowledge of the Hatch-Waxman Act process and in concert with Apotex Corp., directed Apotex's Notice Letter to Novartis, an entity incorporated in Delaware, and alleged in Apotex's Notice Letter that each claim of the Patents-in-Suit is invalid and/or not infringed. On information and belief, Apotex Inc. knowingly and deliberately challenged Novartis's patent rights and knew when it did so that it was triggering the provisions of the Hatch-Waxman Act for Novartis to bring an action for patent infringement.

25. Because Novartis is incorporated in Delaware, Novartis suffers injury and consequences from Apotex Inc.'s filing of Apotex's ANDA, challenging Novartis's patent rights in Delaware. On information and belief, Apotex Inc. knew that it was deliberately challenging the

patent rights of a Delaware entity. Apotex Inc. has been a litigant in connection with at least one other infringement action under the Hatch-Waxman Act and reasonably should have anticipated that by sending Apotex's Notice Letter to Novartis, a Delaware corporation, that it would be sued in Delaware for patent infringement.

26. On information and belief, if Apotex's ANDA is approved, Apotex Inc. will directly or indirectly market, sell, and/or distribute Apotex's ANDA Product within the United States, including in Delaware, consistent with Apotex Inc.'s practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Apotex Inc., including in concert with Apotex Corp., 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, Apotex Inc.'s generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Apotex'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 the claims of the Patents-in-Suit in the event that Apotex's ANDA Product is approved before the patents expire.

27. Alternatively, if Apotex Inc.'s connections with Delaware, including its connections with Apotex Corp., are found to be insufficient to confer personal jurisdiction, then upon information and belief, Apotex Inc. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Apotex Inc. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

28. In addition, this Court has personal jurisdiction over Apotex because Apotex Corp. and Apotex Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Bayer Intellectual Property GmbH et al. v. Apotex Inc. et al.*, Case No. 23-327-RGA, D.I. 11 (D. Del. June 30, 2023); *Bayer Pharma AG et al. v. Apotex Inc. et al.*, Case No. 22-1596-RGA, D.I. 11 (D. Del. Mar. 7, 2023); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Case No. 21-1429-WCB, D.I. 14 (D. Del. Mar. 1, 2022); *Bial-Portela & CA S.A. v. Apotex Inc. et al.*, Case No. 21-187-CFC, D.I. 6 (D. Del. Mar. 3, 2021); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Case No. 20-749-RGA, D.I. 7 (D. Del. June 26, 2020).

VENUE

29. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

30. Venue is proper in this district as to Apotex Corp. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware.

31. Venue is proper in this district for Apotex Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apotex Inc. is a corporation organized and existing under the laws of Canada and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

32. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

33. Mekinist®, which contains trametinib dimethyl sulfoxide, is an anticancer medication indicated for treatment of certain types of melanoma.

34. On information and belief, Apotex's ANDA Product is a generic version of Novartis's Mekinist®.

35. On information and belief, Apotex's ANDA Product is not publicly available, nor is ANDA No. 220471 accessible to the public.

COUNT I – INFRINGEMENT OF THE '304 PATENT

36. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

37. The '304 patent, entitled "Pharmaceutical Composition" (attached as Exhibit A), was duly and legally issued on November 12, 2013.

38. Novartis Pharmaceuticals Corporation is the owner and assignee of the '304 patent.

39. The '304 patent claims, *inter alia*, pharmaceutical tablets comprising trametinib dimethyl sulfoxide solvate, wherein the tablet contains from about 25% to about 89% by weight of one or more excipients, the excipients are substantially free of water, the amount of unsolvated drug does not exceed about 20%, and/or at least 50% of the drug particles have a particle size of 30 microns or less.

40. Mekinist® is covered by one or more claims of the '304 patent, including claims 1 and 8 of the '304 patent, and the '304 patent has been listed in connection with Mekinist® in the FDA's Orange Book.

41. In Apotex's Notice Letter, Apotex notified Novartis of the submission of Apotex'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, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '304 patent.

42. In Apotex's Notice Letter, Apotex also notified Novartis that, as part of its ANDA, Apotex 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 '304 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to

21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the '304 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

43. On information and belief, Apotex's ANDA Product is covered by at least claims 1 and 8 of the '304 patent.

44. On information and belief, Apotex's ANDA Product is a pharmaceutical tablet that contains trametinib dimethyl sulfoxide solvate.

45. On information and belief, Apotex's ANDA Product contains from about 25% to about 89% by weight of one or more excipients that are substantially free of water.

46. On information and belief, the amount of unsolvated drug in Apotex's ANDA Product does not exceed about 20%.

47. On information and belief, at least 50% of the drug particles in Apotex's ANDA Product have a particle size of 30 microns or less.

48. On information and belief, Apotex's submission of Apotex's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '304 patent was an act of infringement of one or more claims of the '304 patent under 35 U.S.C. § 271(e)(2)(A).

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

50. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product would infringe, literally and/or under the doctrine of

equivalents, one or more claims of the '304 patent, including, *inter alia*, claims 1 and 8 of the '304 patent.

51. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '304 patent, including, *inter alia*, claims 1 and 8 of the '304 patent.

52. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '304 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '304 patent and specific intent to infringe that patent.

53. Notwithstanding Apotex's knowledge of the claims of the '304 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling following FDA approval of Apotex's ANDA prior to the expiration of the '304 patent.

54. The foregoing actions by Apotex constitute and/or will constitute infringement of one or more claims of the '304 patent and active inducement of infringement of one or more claims of the '304 patent.

55. Novartis will be substantially and irreparably damaged by infringement of the claims of the '304 patent.

56. Unless Apotex is enjoined from infringing and actively inducing infringement of the claims of the '304 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '304 PATENT

57. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

58. 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 Apotex on the other regarding Apotex's infringement and active inducement of infringement by others of one or more claims of the '304 patent.

59. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the '304 patent, will infringe and induce the infringement by others of the '304 patent.

COUNT III – INFRINGEMENT OF THE '706 PATENT

60. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

61. The '706 patent, entitled "Pharmaceutical Composition" (attached as Exhibit B), was duly and legally issued on October 13, 2015.

62. Novartis Pharmaceuticals Corporation is the owner and assignee of the '706 patent.

63. The '706 patent claims, *inter alia*, pharmaceutical tablets comprising trametinib dimethyl sulfoxide solvate, wherein at least 50% of drug particles have a particle size of 30 microns or less, and/or the drug particles are micronized.

64. Mekinist® is covered by one or more claims of the '706 patent, including claims 1 and 8 of the '706 patent, and the '706 patent has been listed in connection with Mekinist® in the FDA's Orange Book.

65. In Apotex's Notice Letter, Apotex notified Novartis of the submission of Apotex'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, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '706 patent.

66. In Apotex's Notice Letter, Apotex also notified Novartis that, as part of its ANDA, Apotex 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 '706 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the '706 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

67. On information and belief, Apotex's Notice Letter and accompanying statement did not include any allegations that Apotex's ANDA Product does not infringe claims 1, 8 and 16 of the '706 patent.

68. On information and belief, Apotex's ANDA Product is covered by at least claims 1, 8 and 16 of the '706 patent.

69. On information and belief, Apotex's ANDA Product is a pharmaceutical tablet that contains trametinib dimethyl sulfoxide solvate.

70. On information and belief, at least 50% of the drug particles in Apotex's ANDA Product have a particle size of 30 microns or less.

71. On information and belief, the drug particles are micronized in Apotex's ANDA Product.

72. On information and belief, Apotex's submission of Apotex's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale,

and/or importation of Apotex's ANDA Product before the expiration of the '706 patent was an act of infringement of one or more claims of the '706 patent under 35 U.S.C. § 271(e)(2)(A).

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

74. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '706 patent, including, *inter alia*, claims 1, 8, and 16 of the '706 patent.

75. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '706 patent, including, *inter alia*, claims 1, 8, and 16 of the '706 patent.

76. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '706 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '706 patent and specific intent to infringe that patent.

77. Notwithstanding Apotex's knowledge of the claims of the '706 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling following FDA approval of Apotex's ANDA prior to the expiration of the '706 patent.

78. The foregoing actions by Apotex constitute and/or will constitute infringement of one or more claims of the ’706 patent and active inducement of infringement of one or more claims of the ’706 patent.

79. Novartis will be substantially and irreparably damaged by infringement of the claims of the ’706 patent.

80. Unless Apotex is enjoined from infringing and actively inducing infringement of the claims of the ’706 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’706 PATENT

81. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

82. 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 Apotex on the other regarding Apotex’s infringement and active inducement of infringement by others of one or more claims of the ’706 patent.

83. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex’s ANDA Product with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the ’706 patent, will infringe and induce the infringement by others of the ’706 patent.

COUNT V – INFRINGEMENT OF THE ’941 PATENT

84. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

85. The ’941 patent, entitled “Pharmaceutical Composition” (attached as Exhibit C), was duly and legally issued on March 1, 2016.

86. Novartis Pharmaceuticals Corporation is the owner and assignee of the ’941 patent.

87. The ’941 patent claims, *inter alia*, pharmaceutical tablets comprising trametinib dimethyl sulfoxide solvate, wherein the tablets contain from about 25% to about 89% by weight of one or more excipients and the excipients are substantially free of water, and/or at least 50% of the drug particles have a particle size of 30 microns or less.

88. Mekinist® is covered by one or more claims of the ’941 patent, including claims 1 and 8 of the ’941 patent, and the ’941 patent has been listed in connection with Mekinist® in the FDA’s Orange Book.

89. In Apotex’s Notice Letter, Apotex notified Novartis of the submission of Apotex’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, sale, and/or importation of Apotex’s ANDA Product prior to the expiration of the ’941 patent.

90. In Apotex’s Notice Letter, Apotex also notified Novartis that, as part of its ANDA, Apotex 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 ’941 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the ’941 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex’s ANDA Product.

91. On information and belief, Apotex’s ANDA Product is covered by at least claims 1 and 8 of the ’941 patent.

92. On information and belief, Apotex’s ANDA Product is a pharmaceutical tablet that contains trametinib dimethyl sulfoxide solvate.

93. On information and belief, Apotex's ANDA Product contains from about 25% to about 89% by weight of one or more excipients that are substantially free of water.

94. On information and belief, at least 50% of the drug particles in Apotex's ANDA Product have a particle size of 30 microns or less.

95. On information and belief, Apotex's submission of Apotex's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '941 patent was an act of infringement of one or more claims of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

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

97. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '941 patent, including, *inter alia*, claims 1 and 8 of the '941 patent.

98. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '941 patent, including, *inter alia*, claims 1 and 8 of the '941 patent.

99. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '941 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '941 patent and specific intent to infringe that patent.

100. Notwithstanding Apotex's knowledge of the claims of the '941 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling following FDA approval of Apotex's ANDA prior to the expiration of the '941 patent.

101. The foregoing actions by Apotex constitute and/or will constitute infringement of one or more claims of the '941 patent and active inducement of infringement of one or more claims of the '941 patent.

102. Novartis will be substantially and irreparably damaged by infringement of the claims of the '941 patent.

103. Unless Apotex is enjoined from infringing and actively inducing infringement of the claims of the '941 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '941 PATENT

104. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

105. 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 Apotex on the other regarding Apotex's infringement and active inducement of infringement by others of one or more claims of the '941 patent.

106. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the '941 patent, will infringe and induce the infringement by others of the '941 patent.

COUNT VII – INFRINGEMENT OF THE ’021 PATENT

107. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

108. The ’021 patent, entitled “Pharmaceutical Composition” (attached as Exhibit D), was duly and legally issued on July 26, 2016.

109. Novartis Pharmaceuticals Corporation is the owner and assignee of the ’021 patent.

110. The ’021 patent claims, *inter alia*, pharmaceutical tablets comprising trametinib dimethyl sulfoxide solvate, wherein drug particles are micronized, and/or at least 50% of the drug particles have a particle size of 30 microns or less.

111. Mekinist® is covered by one or more claims of the ’021 patent, including claims 1, 8, and 17 of the ’021 patent, and the ’021 patent has been listed in connection with Mekinist® in the FDA’s Orange Book.

112. In Apotex’s Notice Letter, Apotex notified Novartis of the submission of Apotex’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, sale, and/or importation of Apotex’s ANDA Product prior to the expiration of the ’021 patent.

113. In Apotex’s Notice Letter, Apotex also notified Novartis that, as part of its ANDA, Apotex 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 ’021 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the ’021 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex’s ANDA Product.

114. On information and belief, Apotex's Notice Letter and accompanying statement did not include any allegations that Apotex's ANDA Product does not infringe claims 1, 8 and 17 of the '021 patent.

115. On information and belief, Apotex's ANDA Product is covered by at least claims 1, 8, and 17 of the '021 patent.

116. On information and belief, Apotex's ANDA Product is a pharmaceutical tablet that contains trametinib dimethyl sulfoxide solvate.

117. On information and belief, the drug particles in Apotex's ANDA Product are micronized.

118. On information and belief, at least 50% of the drug particles in Apotex's ANDA Product have a particle size of 30 microns or less.

119. On information and belief, Apotex's submission of Apotex's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '021 patent was an act of infringement of one or more claims of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

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

121. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '021 patent, including, *inter alia*, claims 1, 8, and 17 of the '021 patent.

122. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '021 patent, including, *inter alia*, claims 1, 8, and 17 of the '021 patent.

123. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '021 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '021 patent and specific intent to infringe that patent.

124. Notwithstanding Apotex's knowledge of the claims of the '021 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling following FDA approval of Apotex's ANDA prior to the expiration of the '021 patent.

125. The foregoing actions by Apotex constitute and/or will constitute infringement of one or more claims of the '021 patent and active inducement of infringement of one or more claims of the '021 patent.

126. Novartis will be substantially and irreparably damaged by infringement of the claims of the '021 patent.

127. Unless Apotex is enjoined from infringing and actively inducing infringement of the claims of the '021 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '021 PATENT

128. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

129. 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 Apotex on the other regarding Apotex's infringement and active inducement of infringement by others of one or more claims of the '021 patent.

130. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the '021 patent, will infringe and induce the infringement by others of the '021 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

a) A judgment that one or more claims of each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of Apotex's ANDA;

b) A judgment ordering that the effective date of any FDA approval of Apotex's ANDA be not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

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

d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more claims of one or more of the Patents-

in-Suit, prior to the expiration of the Patents-in-Suit, will infringe and/or induce the infringement of the patents;

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

f) Novartis's costs and expenses in this action; and

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

Dated: October 30, 2025

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