IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG, and JAPAN TOBACCO INC., *Plaintiffs,* v. NOVUGEN ONCOLOGY SDN. BHD., NOVUGEN PHARMA (USA) LLC, and MAKRO TECHNOLOGIES, INC., *Defendants.*	Civil Action No. _____

COMPLAINT

1. Plaintiffs Novartis Pharmaceuticals Corporation and Novartis Pharma AG (collectively, "Novartis") and Japan Tobacco Inc. ("Japan Tobacco") (Novartis and Japan Tobacco collectively, "Plaintiffs") file this Complaint for patent infringement against Novugen Oncology Sdn. Bhd., Novugen Pharma (USA) LLC, and Makro Technologies, Inc. (collectively, "Novugen"), and by their attorneys, hereby allege 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 Novugen'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 Mekinist® (trametinib dimethyl sulfoxide) tablets, 0.5 mg and 2 mg, prior to the expiration of U.S. Patent No. 7,378,423 ("the '423 patent"); 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. Novugen notified Plaintiffs by letter dated November 7, 2023 ("Novugen's Notice Letter") that it had submitted to the FDA ANDA No. 219002 ("Novugen'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, ("Novugen's ANDA Product") prior to the expiration of the Patents-in-Suit.

PARTIES

4. Plaintiffs incorporate 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 One Health Plaza, 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. Plaintiff Novartis Pharma AG is a Swiss corporation having a principal place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

7. Plaintiff Japan Tobacco Inc. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Toranomon 4-Chome, Minato-Ku, Tokyo 105-6927, Japan.

8. On information and belief, Defendant Novugen Oncology Sdn. Bhd. (formerly known as Oncogen Pharma (Malaysia) Sdn. Bhd.) is a corporation organized and existing under

the laws of Malaysia, having a principal place of business at No. 3, Jalan Jururancang U1/21, Hicom-glenmarie Industrial Park, 40150 Shah Alam, Selangor, Malaysia.

9. On information and belief, Defendant Novugen Pharma (USA) LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 100 Overlook Center, 2nd Floor, Princeton, New Jersey 08540.

10. On information and belief, Defendant Novugen Pharma (USA) LLC acts at the direction, and for the benefit, of Novugen Oncology Sdn. Bhd., and is controlled and/or dominated by Novugen Oncology Sdn. Bhd. Alternatively, on information and belief, Novugen Pharma (USA) LLC and Novugen Oncology Sdn. Bhd. act at the direction, and for the benefit, of a common corporate parent and are controlled and/or dominated by said common corporate parent.

11. On information and belief, Defendant Makro Technologies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4 Independence Way, Suite 110, Princeton, New Jersey 08540.

12. On information and belief, Makro Technologies, Inc. is the U.S. agent for Novugen Oncology Sdn. Bhd. and acts at the direction, and for the benefit, of Novugen Oncology Sdn. Bhd.

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

JURISDICTION

14. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

16. This Court has personal jurisdiction over Defendant Novugen Oncology Sdn. Bhd.

17. Novugen Oncology Sdn. Bhd. 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, Novugen Oncology Sdn. Bhd., acting in concert with Novugen Pharma (USA) LLC, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Novartis's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

18. On information and belief, Novugen Oncology Sdn. Bhd. knows and intends that following any approval of Novugen's ANDA No. 219002, Novugen Oncology Sdn. Bhd. will, in concert with Novugen Pharma (USA) LLC, manufacture and import into the United States Novugen's ANDA Product and directly or indirectly market, sell, and distribute Novugen's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 219002, Novugen Oncology Sdn. Bhd. knows and intends that Novugen's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

19. Novugen Oncology Sdn. Bhd. 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.

20. On information and belief, Novugen Oncology Sdn. Bhd., with knowledge of the Hatch-Waxman Act process, directed Novugen's Notice Letter to, *inter alia*, Novartis

Pharmaceuticals Corporation, an entity incorporated in Delaware, and alleged in Novugen's Notice Letter that all of the Patents-in-Suit are invalid and/or not infringed. On information and belief, Novugen Oncology Sdn. Bhd. 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.

21. Because Novartis Pharmaceuticals Corporation is incorporated in Delaware, Novartis suffers injury and consequences from Novugen Oncology Sdn. Bhd.'s filing of Novugen's ANDA, challenging Novartis's patent rights in Delaware. On information and belief, Novugen Oncology Sdn. Bhd. knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Novugen Oncology Sdn. Bhd. 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 Novugen's Notice Letter to Novartis Pharmaceuticals Corporation, a Delaware corporation, that it would be sued in Delaware for patent infringement.

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

and belief, Novugen'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 Plaintiffs' patents in the event that Novugen's ANDA Product is approved before the patents expire.

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

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

25. This Court has personal jurisdiction over Defendant Novugen Pharma (USA) LLC.

26. Novugen Pharma (USA) LLC 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. Novugen Pharma (USA) LLC. is a limited liability company 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 251 Little Falls Drive, Wilmington, Delaware 19808. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Novugen Pharma (USA) LLC, acting in concert with Novugen Oncology Sdn. Bhd., 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.

27. On information and belief, Novugen Pharma (USA) LLC knows and intends that following any approval of Novugen's ANDA No. 219002, Novugen Pharma (USA) LLC will, in concert with Novugen Oncology Sdn. Bhd., manufacture and import into the United States Novugen's ANDA Product and directly or indirectly market, sell, and distribute Novugen's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 219002, Novugen Pharma (USA) LLC knows and intends that Novugen's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

28. Novugen Pharma (USA) LLC 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.

29. On information and belief, Novugen Pharma (USA) LLC, with knowledge of the Hatch-Waxman Act process, directed Novugen's Notice Letter to, *inter alia*, Novartis Pharmaceuticals Corporation, an entity incorporated in Delaware, and alleged in Novugen's Notice

Letter that all of the Patents-in-Suit are invalid and/or not infringed. On information and belief, Novugen Pharma (USA) LLC 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.

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

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

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

33. This Court has personal jurisdiction over Defendant Makro Technologies, Inc.

34. Makro Technologies, 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. Makro Technologies, 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 located at 8 The Green, Suite A, Dover, Delaware 19901. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Makro Technologies, Inc. aided in the preparation and submission of ANDA No. 219002 and continues to act collaboratively with Novugen Oncology Sdn. Bhd. and Novugen Pharma (USA) LLC in pursuing FDA approval of ANDA No. 219002 and the sale of Novugen's ANDA Product throughout the United States, including in 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.

35. On information and belief, Makro Technologies, Inc. knows and intends that following any approval of Novugen's ANDA No. 219002, Novugen Oncology Sdn. Bhd. and Novugen Pharma (USA) LLC will manufacture and import into the United States Novugen's ANDA Product and directly or indirectly market, sell, and distribute Novugen's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 219002, Makro Technologies, Inc. knows and intends that Novugen's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

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

VENUE

37. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

38. Venue is proper in this district for Novugen Oncology Sdn. Bhd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Novugen Oncology Sdn. Bhd. is a corporation

organized and existing under the laws of Malaysia and is subject to personal jurisdiction in this judicial district.

39. Venue is proper in this district as to Novugen Pharma (USA) LLC pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Novugen Pharma (USA) LLC is a limited liability company organized and existing under the laws of the State of Delaware.

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

FACTUAL BACKGROUND

41. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

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

44. On information and belief, Novugen's ANDA Product is not publicly available, nor is ANDA No. 219002 accessible to the public.

45. In Novugen's Notice Letter, Novugen included an Offer of Confidential Access to portions of ANDA No. 219002. Plaintiffs received Novugen's ANDA under a modified version of Novugen's Offer of Confidential Access.

COUNT I – INFRINGEMENT OF THE '423 PATENT

46. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

47. The '423 patent, entitled "Pyrimidine Compound and Medical Use Thereof" (attached as Exhibit A), was duly and legally issued on May 27, 2008.

48. Japan Tobacco is the owner and assignee of the ’423 patent.

49. Novartis Pharma AG is the exclusive licensee of the ’423 patent.

50. Plaintiffs collectively possess all exclusive rights and interests in the ’423 patent.

51. The ’423 patent claims, *inter alia*, a compound with the formula recited in claim 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof. The ’423 patent also claims, *inter alia*, a pharmaceutical composition comprising a compound with the formula recited in claim 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof and a pharmaceutically acceptable carrier.

52. Mekinist® is covered by one or more claims of the ’423 patent, including claims 1, 13, 17, and 25 of the ’423 patent, and the ’423 patent has been listed in connection with Mekinist® in the FDA’s Orange Book.

53. In Novugen’s Notice Letter, Novugen notified Plaintiffs of the submission of Novugen’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 Novugen’s ANDA Product prior to the expiration of the ’423 patent.

54. In Novugen’s Notice Letter, Novugen also notified Plaintiffs that, as part of its ANDA, Novugen 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 ’423 patent. On information and belief, Novugen submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’423 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Novugen’s ANDA Product.

55. On information and belief, Novugen's ANDA Product is covered by at least claims 1, 13, 17, and 25 of the '423 patent.

56. On information and belief, Novugen's ANDA Product contains trametinib dimethyl sulfoxide solvate.

57. On information and belief, Novugen's ANDA Product is a pharmaceutical composition that contains a pharmaceutically acceptable carrier.

58. In Novugen's Notice Letter, Novugen did not contest the infringement of claims 1, 13, 17, and 25 of the '423 patent on any basis other than the alleged invalidity of those claims.

59. Novugen's submission of Novugen's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Novugen's ANDA Product before the expiration of the '423 patent was an act of infringement of the '423 patent under 35 U.S.C. § 271(e)(2)(A).

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

61. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '423 patent, including, *inter alia*, claims 1, 13, 17, and 25 of the '423 patent.

62. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '423 patent, including, *inter alia*, claims 1, 13, 17, and 25 of the '423 patent.

63. On information and belief, Novugen plans and intends to, and will, actively induce infringement of the '423 patent when Novugen's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Novugen's activities will be done with knowledge of the '423 patent and specific intent to infringe that patent.

64. On information and belief, Novugen knows that Novugen's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '423 patent, that Novugen's ANDA Product is not a staple article or commodity of commerce, and that Novugen's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Novugen plans and intends to, and will, contribute to infringement of the '423 patent immediately and imminently upon approval of Novugen's ANDA.

65. Notwithstanding Novugen's knowledge of the claims of the '423 patent, Novugen has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Novugen's ANDA Product with its product labeling following FDA approval of Novugen's ANDA prior to the expiration of the '423 patent.

66. The foregoing actions by Novugen constitute and/or will constitute infringement of the '423 patent; active inducement of infringement of the '423 patent; and contribution to the infringement by others of the '423 patent.

67. Plaintiffs will be substantially and irreparably damaged by infringement of the '423 patent.

68. Unless Novugen is enjoined from infringing the '423 patent, actively inducing infringement of the '423 patent, and contributing to the infringement by others of the '423 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '423 PATENT

69. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

70. 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 Plaintiffs on the one hand and Novugen on the other regarding Novugen's infringement, active inducement of infringement, and contribution to the infringement by others of the '423 patent.

71. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Novugen's ANDA Product with its proposed labeling, or any other Novugen drug product that is covered by or whose use is covered by the '423 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '423 patent.

COUNT III – INFRINGEMENT OF THE '304 PATENT

72. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

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

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

75. 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 micron or less.

76. Mekinist® is covered by one or more claims of the '304 patent, including at least 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.

77. In Novugen's Notice Letter, Novugen notified Plaintiffs of the submission of Novugen'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 Novugen's ANDA Product prior to the expiration of the '304 patent.

78. In Novugen's Notice Letter, Novugen also notified Plaintiffs that, as part of its ANDA, Novugen 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, Novugen submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '304 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Novugen's ANDA Product.

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

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

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

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

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

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

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

86. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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.

87. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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.

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

89. On information and belief, Novugen knows that Novugen's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '304 patent, that Novugen's ANDA Product is not a staple article or commodity of commerce, and that Novugen's

ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Novugen plans and intends to, and will, contribute to infringement of the '304 patent immediately and imminently upon approval of Novugen's ANDA.

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

91. The foregoing actions by Novugen constitute and/or will constitute infringement of the '304 patent; active inducement of infringement of the '304 patent; and contribution to the infringement by others of the '304 patent.

92. Plaintiffs will be substantially and irreparably damaged by infringement of the '304 patent.

93. Unless Novugen is enjoined from infringing the '304 patent, actively inducing infringement of the '304 patent, and contributing to the infringement by others of the '304 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

94. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

95. 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 Plaintiffs on the one hand and Novugen on the other regarding Novugen's infringement, active inducement of infringement, and contribution to the infringement by others of the '304 patent.

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

COUNT V – INFRINGEMENT OF THE '706 PATENT

97. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

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

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

100. 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.

101. 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.

102. In Novugen's Notice Letter, Novugen notified Plaintiffs of the submission of Novugen'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 Novugen's ANDA Product prior to the expiration of the '706 patent.

103. In Novugen's Notice Letter, Novugen also notified Plaintiffs that, as part of its ANDA, Novugen 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, Novugen submitted its ANDA to the FDA containing certifications pursuant to

21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '706 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Novugen's ANDA Product.

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

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

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

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

108. In Novugen's Notice Letter, Novugen did not contest the infringement of claims 1 and 8 of the '706 patent on any basis other than the alleged invalidity of that claim.

109. Novugen's submission of Novugen's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Novugen's ANDA Product before the expiration of the '706 patent was an act of infringement of the '706 patent under 35 U.S.C. § 271(e)(2)(A).

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

111. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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 and 8 of the '706 patent.

112. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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 and 8 of the '706 patent.

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

114. On information and belief, Novugen knows that Novugen's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '706 patent, that Novugen's ANDA Product is not a staple article or commodity of commerce, and that Novugen's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Novugen plans and intends to, and will, contribute to infringement of the '706 patent immediately and imminently upon approval of Novugen's ANDA.

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

116. The foregoing actions by Novugen constitute and/or will constitute infringement of the '706 patent; active inducement of infringement of the '706 patent; and contribution to the infringement by others of the '706 patent.

117. Plaintiffs will be substantially and irreparably damaged by infringement of the '706 patent.

118. Unless Novugen is enjoined from infringing the '706 patent, actively inducing infringement of the '706 patent, and contributing to the infringement by others of the '706 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '706 PATENT

119. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

120. 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 Plaintiffs on the one hand and Novugen on the other regarding Novugen's infringement, active inducement of infringement, and contribution to the infringement by others of the '706 patent.

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

COUNT VII – INFRINGEMENT OF THE '941 PATENT

122. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

123. The '941 patent, entitled "Pharmaceutical Composition" (attached as Exhibit D), was duly and legally issued on March 1, 2016.

124. Novartis Pharmaceuticals Corporation is the owner and assignee of the '941 patent.

125. 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 micron or less.

126. 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.

127. In Novugen's Notice Letter, Novugen notified Plaintiffs of the submission of Novugen'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 Novugen's ANDA Product prior to the expiration of the '941 patent.

128. In Novugen's Notice Letter, Novugen also notified Plaintiffs that, as part of its ANDA, Novugen 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, Novugen submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '941 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Novugen's ANDA Product.

129. On information and belief, Novugen's ANDA Product is covered by at least claims 1 and 8 of the '941 patent.

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

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

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

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

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

135. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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.

136. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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.

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

138. On information and belief, Novugen knows that Novugen's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '941 patent, that Novugen's ANDA Product is not a staple article or commodity of commerce, and that Novugen's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On

information and belief, Novugen plans and intends to, and will, contribute to infringement of the '941 patent immediately and imminently upon approval of Novugen's ANDA.

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

140. The foregoing actions by Novugen constitute and/or will constitute infringement of the '941 patent; active inducement of infringement of the '941 patent; and contribution to the infringement by others of the '941 patent.

141. Plaintiffs will be substantially and irreparably damaged by infringement of the '941 patent.

142. Unless Novugen is enjoined from infringing the '941 patent, actively inducing infringement of the '941 patent, and contributing to the infringement by others of the '941 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

143. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

144. 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 Plaintiffs on the one hand and Novugen on the other regarding Novugen's infringement, active inducement of infringement, and contribution to the infringement by others of the '941 patent.

145. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Novugen's ANDA Product with its proposed labeling, or any other Novugen

drug product that is covered by or whose use is covered by the ’941 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’941 patent.

COUNT IX – INFRINGEMENT OF THE ’021 PATENT

146. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

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

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

149. 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 micron or less.

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

151. In Novugen’s Notice Letter, Novugen notified Plaintiffs of the submission of Novugen’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 Novugen’s ANDA Product prior to the expiration of the ’021 patent.

152. In Novugen’s Notice Letter, Novugen also notified Plaintiffs that, as part of its ANDA, Novugen 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, Novugen submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’021 patent is invalid, unenforceable, and/or will not be

infringed by the manufacture, use, offer for sale, sale, and/or importation of Novugen's ANDA Product.

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

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

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

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

157. In Novugen's Notice Letter, Novugen did not contest the infringement of claims 1 and 8 of the '021 patent on any basis other than the alleged invalidity of that claim.

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

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

160. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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 and 8 of the '021 patent.

161. On information and belief, the manufacture, use, sale, offer for sale, or importation of Novugen'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 and 8 of the '021 patent.

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

163. On information and belief, Novugen knows that Novugen's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 patent, that Novugen's ANDA Product is not a staple article or commodity of commerce, and that Novugen's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Novugen plans and intends to, and will, contribute to infringement of the '021 patent immediately and imminently upon approval of Novugen's ANDA.

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

165. The foregoing actions by Novugen constitute and/or will constitute infringement of the '021 patent; active inducement of infringement of the '021 patent; and contribution to the infringement by others of the '021 patent.

166. Plaintiffs will be substantially and irreparably damaged by infringement of the '021 patent.

167. Unless Novugen is enjoined from infringing the ’021 patent and/or actively inducing infringement of the ’021 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’021 PATENT

168. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

169. 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 Plaintiffs on the one hand and Novugen on the other regarding Novugen’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’021 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request 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 Novugen’s submission to the FDA of Novugen’s ANDA;

b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Novugen’s ANDA Product, or any other drug product that infringes or the use of which infringes one or more claims of 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 Novugen, and all persons acting in concert with Novugen, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Novugen'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 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 Novugen'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 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: December 20, 2023

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