IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION

Plaintiff,

v.

Civil Action No. _____

HANDA NEUROSCIENCE, LLC, HANDA PHARMACEUTICALS, INC., HANDA PHARMA, INC., and HANDA PHARMACEUTICALS, LLC

Defendants.

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis") by its attorneys hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.*. This action relates to a New Drug Application ("NDA") filed under 21 U.S.C. § 355(b)(2) by the above-named defendants (collectively, "Handa") with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of Fingolimod Orally Disintegrating Tablets 0.5 mg, a version of Novartis's GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent Nos. 9,187,405 ("the '405 patent") and 10,543,179 ("the '179 patent").

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

B. Handa

3. Upon information and belief, Defendant Handa Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Taiwan, having a principal place of business at 3F-1&3F-2, No.23, Nanke 3rd Rd., Tainan City 74147, Taiwan.

4. Upon information and belief, Defendant Handa Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1732 N. First Street, Suite 200 San Jose, California 95112. Upon information and belief, Handa Pharma, Inc. is a wholly-owned subsidiary of Handa Pharmaceuticals, Inc.

5. Upon information and belief, Defendant Handa Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 1732 N. First Street, Suite 200 San Jose, California 95112. Upon information and belief, Handa Pharmaceuticals, LLC is a wholly-owned subsidiary of Handa Pharma, Inc.

6. Upon information and belief, Defendant Handa Neuroscience, LLC is a limited liability company organized and existing under the laws of California, having a principal place of business at 1732 N. First Street, Suite 200 San Jose, California 95112. Upon information and belief, Handa Neuroscience, LLC is a wholly-owned subsidiary of Handa Pharma, Inc.

7. Handa notified Plaintiff that Handa had, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(b)(2)), submitted to FDA NDA No.

214962 ("the 505(b)(2) NDA") for Fingolimod Orally Disintegrating Tablets 0.5 mg, a drug product that is a version of GILENYA® ("the 505(b)(2) Product"). The purpose of Handa's submission of the 505(b)(2) NDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Handa's 505(b)(2) NDA Product prior to the expiration of the '405 and '179 patents.

8. Handa notified Plaintiff that, as a part of its 505(b)(2) NDA, Handa had filed a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA (21 U.S.C. § 355(b)(2)(A)(iv)) with respect to the '405 and '179 patents asserting that both patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Handa's 505(b)(2) NDA Product.

9. Handa has committed an act of infringement in this judicial district by filing NDA No. 214962 with the intent to make, use, offer to sell, and/or sell the drug products that are the subject of NDA No. 214962 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

10. Upon information and belief, Handa Pharmaceuticals, Inc., Handa Pharma, Inc., Handa Pharmaceuticals, LLC, and Handa Neuroscience, LLC acted collaboratively in the preparation and submission of NDA No. 214962 and upon information and belief will work in concert with one another to make, use, offer to sell, and/or sell the drug products that are the subject of NDA No. 214962 throughout the United States, and/or import such drug products into the United States, including in this judicial district.

11. Upon information and belief, Handa's overall business strategy comprises utilizing its Taiwan headquarters as its global R&D center and establishing its presence in the U.S. market through its U.S. subsidiaries.

12. Upon information and belief, Handa Pharmaceuticals, Inc. is Handa's headquarters and global research and development center; Handa Pharma, Inc. is responsible for business development, intellectual property, and regulatory affairs; Handa Pharmaceuticals, LLC is responsible for Generics Business; and Handa Neuroscience, LLC is responsible for Brand Products – Neuroscience.

13. Upon information and belief, Handa Pharma, Inc., Handa Pharmaceuticals, LLC, and Handa Neuroscience, LLC ("the Handa US Entities") share an office in San Jose, California.

14. Upon information and belief, Dr. Fangyu Liu is the founder, President, and Chairman of the Board of Directors of Handa Pharmaceuticals, Inc. Upon information and belief, Dr. Liu is also the President of Handa Pharma, Inc., the Manager of Handa Pharmaceuticals, LLC, and the CEO and agent for the service of process of Handa Neuroscience LLC.

15. Upon information and belief, Dr. Liu is the sole inventor listed on U.S. Patent Nos. 9,925,138, 10,555,902, and 10,925,829 ("Liu Patents").

16. Upon information and belief, the Liu Patents are directed to subject matter related to Handa's 505(b)(2) NDA Product.

17. Upon information and belief, Handa refers to its 505(b)(2) NDA Product as "HND-020," an orally disintegrating tablet indicated for Multiple Sclerosis. Upon information and belief, Handa Pharmaceuticals, Inc. first successfully manufactured a pilot batch of its 505(b)(2) NDA Product in 2018.

18. Upon information and belief, in October 2019, Dr. Liu assigned the Liu Patents to Handa Pharmaceuticals, LLC.

19. Upon information and belief, Handa Neuroscience, LLC was incorporated on July 17, 2020.

20. Upon information and belief, in August 2020, Handa Pharmaceuticals, LLC assigned the Liu Patents to Handa Neuroscience, LLC.

21. Upon information and belief, Handa submitted its 505(b)(2) NDA to FDA on December 18, 2020. Handa indicated in its notice to Novartis that Handa Neuroscience, LLC is the sponsor of NDA No. 214962, Handa's 505(b)(2) NDA.

22. Upon information and belief, Handa Neuroscience, LLC acted as an agent for and at the direction and control of Handa Pharmaceuticals, Inc., including through its other agents Handa Pharma, Inc. and Handa Pharmaceuticals, LLC, in submitting the 505(b)(2) NDA to FDA.

23. Upon information and belief, Handa Pharmaceuticals, Inc. dominates and controls the affairs of the Handa US Entities such that the Handa US Entities are alter egos of Handa Pharmaceuticals, Inc.

24. Upon information and belief, Handa Pharmaceuticals, Inc. has extensive contacts with the State of Delaware, including through its subsidiaries Handa Pharma, Inc. and Handa Pharmaceuticals, LLC, and regularly does business in this District, including through its subsidiaries Handa Pharma, Inc. and Handa Pharmaceuticals, LLC.

25. Handa Pharmaceuticals, Inc. has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for Handa Pharma, Inc. and Handa Pharmaceuticals, Inc.

26. Upon information and belief, Handa Pharma, Inc. is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this

District. Moreover, upon information and belief, Handa Pharma, Inc. has appointed a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process.

27. Handa Pharma, Inc. has extensive contacts with the State of Delaware, including through its subsidiary Handa Pharmaceuticals, LLC, and upon information and belief regularly does business in this District, including through its subsidiary Handa Pharmaceuticals, LLC.

28. Upon information and belief, Handa Pharmaceuticals, LLC is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this District. Moreover, upon information and belief, Handa Pharmaceuticals, LLC has appointed a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process.

29. Handa Pharmaceuticals, LLC has extensive contacts with the State of Delaware and upon information and belief regularly does business in this District.

30. Handa Pharmaceuticals, LLC has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation and admitting jurisdiction and filing counterclaims in the United States District Court for the District of Delaware. *See, e.g.*, *Purdue Pharma Products L.P. v. Handa Pharmaceuticals LLC*, C.A. No. 10-00208-KAJ (D. Del.); *J M Smith Corporation v. AstraZeneca Pharmaceuticals L.P.*, C.A. No. 19-7233-CM, D.I. 68-1 (S.D.N.Y. October 31, 2019) (Arguing on motion to dismiss for lack of personal jurisdiction and improper venue, or in the alternative, to transfer pursuant to 28 U.S.C. § 1404 that Delaware was a proper jurisdiction for Handa Pharmaceuticals, LLC).

JURISDICTION AND VENUE

31. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

32. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, induced, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing the 505(b)(2) NDA that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

33. This Court also has personal jurisdiction over each Defendant because each of its affiliations with the State of Delaware, including by virtue of Handa Pharma, Inc.'s and Handa Pharmaceuticals, LLC's incorporation in Delaware, are so continuous and systematic as to render each Defendant essentially at home in this forum.

34. This Court also has personal jurisdiction over each Defendant because Handa has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for Handa Pharma, Inc. and Handa Pharmaceuticals, LLC, and admitting jurisdiction and filing counterclaims in this district.

35. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

36. Venue is proper in this Court under both 28 U.S.C. § 1400(b) and 28 U.S.C. § 1391 because each Handa US Entity is *inter alia* incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this District. Handa Pharmaceuticals, Inc. is a foreign corporation not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

GILENYA®

37. Novartis is the holder of New Drug Application ("NDA") No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

THE PATENTS-IN-SUIT

38. On November 17, 2015, the U.S. Patent and Trademark Office duly and legally issued the '405 patent, entitled "S1P Receptor Modulators for Treating Relasping[*sic*]-Remitting Multiple Sclerosis." A true and correct copy of the '405 patent is attached hereto as **Exhibit A**.

39. Claim 1 of the '405 patent recites: "A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject [fingolimod], in free form or in a pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." Independent claims 3 and 5 are similar to claim 1 but recite methods for "treating Relapsing-Remitting multiple sclerosis" and "slowing progression of Relapsing-Remitting multiple sclerosis" in subjects in need thereof. Dependent claims 2, 4, and 6 recite the further limitation that fingolimod hydrochloride is administered.

40. The claims of the ’405 patent are neither invalid nor unenforceable, as held by this Court in a final judgment dated September 11, 2020 (*Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc.*, C.A. No. 18-1043-KAJ, D.I. 780 (D. Del.)), and as previously held by the United States Patent and Trademark Office in its Final Written Decision following *inter partes* review. *See Apotex Inc. v. Novartis A.G.*, IPR2017-00854, 2018 WL 3414289 (P.T.A.B. July 11, 2018). The ’405 patent is wholly owned by Novartis, which therefore has the right to sue for and obtain equitable relief and damages for infringement of the ’405 patent.

41. GILENYA® and the use of GILENYA® is covered by one or more claims of the ’405 patent.

42. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’405 patent in connection with GILENYA®.

43. On January 28, 2020, the U.S. Patent and Trademark Office duly and legally issued the ’179 patent, entitled “Dosage Regimen of an S1P Receptor Modulator.” A true and correct copy of the ’179 patent is attached hereto as **Exhibit B**.

44. Claim 1 of the ’179 patent recites: “A method for treating relapsing remitting multiple sclerosis in a patient in need thereof, the method comprising: (a) identifying a patient at risk of contracting infection caused by varicella zoster virus by testing said patient for a history of infection caused by varicella zoster virus, (b) vaccinating the patient at risk of contracting infection caused by varicella zoster virus, and (c) administering orally fingolimod or a pharmaceutically acceptable salt thereof to said patient at a daily dosage of 0.5 mg.” Claims 2, 3, and 4, which each depend from claim 1, recite further limitations: that “treating comprises reducing the frequency of clinical exacerbations”; that “fingolimod is administered as a hydrochloride salt”; and that “the infection is chickenpox.”

45. The claims of the '179 patent are neither invalid nor unenforceable. The '179 patent is wholly owned by Novartis, which therefore has the right to sue for and obtain equitable relief and damages for infringement of the '179 patent.

46. GILENYA® and the use of GILENYA® is covered by one or more claims of the '179 patent.

47. The FDA's official publication of approved drugs (the "Orange Book") lists the '179 patent in connection with GILENYA®.

COUNT I: INFRINGEMENT BY EACH DEFENDANT OF THE '405 PATENT UNDER 35 U.S.C. 271(e)

48. Plaintiff incorporates each of the preceding paragraphs 1 – 47 as if fully set forth herein.

49. Handa has notified Novartis of its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its 505(b)(2) NDA Product prior to the expiration of the '405 patent.

50. Handa's 505(b)(2) NDA submission seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its 505(b)(2) NDA Product, prior to the expiration of the '405 patent constitutes infringement of one or more of the claims of the '405 patent under 35 U.S.C. § 271(e)(2)(A).

51. Upon information and belief, Handa intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its 505(b)(2) NDA Product with its proposed labeling immediately and imminently upon final approval of its 505(b)(2) NDA.

52. Handa, by filing its 505(b)(2) NDA, has represented to the FDA that, upon approval, its 505(b)(2) NDA Product will have the same active ingredient or a pharmaceutically

acceptable salt thereof and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®. Specifically, Handa has indicated to Novartis that its 505(b)(2) NDA Product contains the same drug in the same dosage amount as GILENYA®, and that Handa's 505(b)(2) NDA contains the bioavailability and/or bioequivalence data and information from studies of Handa's 505(b)(2) NDA Product.

53. Handa has indicated that its 505(b)(2) NDA Product is orally administered and contains 0.5 mg fingolimod.

54. FDA regulations require that Handa's 505(b)(2) NDA Product labeling instruct that its 505(b)(2) NDA Product be administered for approved indications at approved dosages. *See* 21 U.S.C. § 355(d) (setting forth that FDA may reject an NDA that does not contain reports showing "adequate tests by all methods reasonably applicable to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof"); 21 C.F.R. § 201.57(c)(2)(iv) (requiring that "all indications listed in [the Indications and Usage] section [of the drug labeling] must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b)," where § 314.126(b) provides placebo concurrent control, dose-comparison concurrent control, and active treatment concurrent control as examples).

55. Upon information and belief, the only FDA-approved indication for fingolimod, and the only indication adequately supported by adequate tests and studies, is the same as that of Novartis's GILENYA® product and that recited in at least claim 1 of the '405 patent, specifically the treatment of relapsing-remitting multiple sclerosis, including by "reducing or preventing or alleviating relapses."

56. Upon information and belief, FDA has not approved for any indication the administration of fingolimod at a dose higher than 0.5 mg orally once daily, and therefore Handa's label will indicate that Handa's 505(b)(2) NDA product should be administered "absent an immediately preceding loading dose."

57. Thus, upon information and belief, Handa's 505(b)(2) NDA Product labeling will disclose all elements of at least claim 1 of the '405 patent, therefore showing that use by, for example, patients and/or healthcare providers of Handa's 505(b)(2) NDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '405 patent.

58. Upon information and belief, Handa's 505(b)(2) NDA Product's proposed labeling will instruct, for example, patients and/or healthcare providers to perform all elements of at least claim 1 of the '405 patent.

59. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Handa's 505(b)(2) NDA Product would infringe one or more claims of the '405 patent.

60. Upon information and belief, use of Handa's 505(b)(2) NDA Product in accordance with and as directed by its proposed labeling would infringe one or more claims of the '405 patent.

61. Upon information and belief, Handa will have actual knowledge of the '405 patent and will actively induce infringement of the '405 patent when its 505(b)(2) NDA is approved, and will do so immediately and imminently upon final approval.

62. Upon information and belief, Handa will know that its 505(b)(2) NDA Product is especially made or adapted for use in infringing the '405 patent, and that its 505(b)(2) NDA Product is not suitable for any substantial non-infringing use. Upon information and belief,

Handa will contribute to the infringement of the ’405 patent immediately and imminently upon approval of its 505(b)(2) NDA.

63. The foregoing acts by Handa constitute and/or will constitute active inducement of infringement of the ’405 patent and/or contribution to the infringement by others of the ’405 patent under 35 U.S.C. §§ 271(b) and (c).

64. If Handa’s infringement of the ’405 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT BY EACH DEFENDANT OF THE ’405 PATENT UNDER 35 U.S.C. 271(b) AND (c)

65. Plaintiff incorporates each of the preceding paragraphs 1 – 64 as if fully set forth herein.

66. Upon information and belief, Handa intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its 505(b)(2) NDA Product with its proposed labeling immediately and imminently upon final approval of its 505(b)(2) NDA. Therefore a case or controversy exists between each Defendant or group of Defendants and Novartis as to infringement of the ’405 patent.

67. Handa, by filing its 505(b)(2) NDA, has represented to the FDA that, upon approval, its 505(b)(2) NDA Product will have the same active ingredient or a pharmaceutically acceptable salt thereof and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®. Specifically, Handa has indicated to Novartis that its 505(b)(2) NDA Product contains the same drug in the same dosage amount as GILENYA®, and that Handa’s 505(b)(2) NDA contains the bioavailability and/or bioequivalence data and information from studies of Handa’s 505(b)(2) NDA Product.

68. Handa has indicated that its 505(b)(2) NDA Product is orally administered and contains 0.5 mg fingolimod.

69. FDA regulations require that Handa's 505(b)(2) NDA Product labeling instruct that its 505(b)(2) NDA Product be administered for approved indications at approved dosages. *See* 21 U.S.C. § 355(d) (setting forth that FDA may reject an NDA that does not contain reports showing "adequate tests by all methods reasonably applicable to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof"); 21 C.F.R. § 201.57(c)(2)(iv) (requiring that "all indications listed in [the Indications and Usage] section [of the drug labeling] must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b)," where § 314.126(b) provides placebo concurrent control, dose-comparison concurrent control, and active treatment concurrent control as examples).

70. Upon information and belief, the only FDA-approved indication for fingolimod, and the only indication adequately supported by adequate tests and studies, is the same as that of Novartis's GILENYA® product and that recited in at least claim 1 of the '405 patent, specifically the treatment of relapsing-remitting multiple sclerosis, including by "reducing or preventing or alleviating relapses."

71. Upon information and belief, FDA has not approved for any indication the administration of fingolimod at a dose higher than 0.5 mg orally once daily, and therefore Handa's label will indicate that Handa's 505(b)(2) NDA product should be administered "absent an immediately preceding loading dose."

72. Thus, upon information and belief, Handa's 505(b)(2) NDA Product labeling will disclose all elements of at least claim 1 of the '405 patent, therefore showing that use

by, for example, patients and/or healthcare providers of Handa's 505(b)(2) NDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '405 patent.

73. Upon information and belief, Handa's 505(b)(2) NDA Product's proposed labeling will instruct, for example, patients and/or healthcare providers to perform all elements of at least claim 1 of the '405 patent.

74. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Handa's 505(b)(2) NDA Product would infringe one or more claims of the '405 patent.

75. Upon information and belief, use of Handa's 505(b)(2) NDA Product in accordance with and as directed by its proposed labeling would infringe one or more claims of the '405 patent.

76. Upon information and belief, Handa will have actual knowledge of the '405 patent and will actively induce infringement of the '405 patent when its 505(b)(2) NDA is approved, and will do so immediately and imminently upon final approval.

77. Upon information and belief, Handa will know that its 505(b)(2) NDA Product is especially made or adapted for use in infringing the '405 patent, and that its 505(b)(2) NDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Handa will contribute to the infringement of the '405 patent immediately and imminently upon approval of its 505(b)(2) NDA.

78. The foregoing acts by Handa constitute and/or will constitute active inducement of infringement of the '405 patent and/or contribution to the infringement by others of the '405 patent under 35 U.S.C. §§ 271(b) and (c).

79. If Handa's infringement of the '405 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT BY EACH DEFENDANT OF THE '179 PATENT UNDER 35 U.S.C. 271(e)

80. Plaintiff incorporates each of the preceding paragraphs 1 – 79 as if fully set forth herein.

81. Handa has notified Novartis of its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its 505(b)(2) NDA Product prior to the expiration of the '179 patent.

82. Handa's 505(b)(2) NDA submission seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its 505(b)(2) NDA Product, prior to the expiration of the '179 patent constitutes infringement of one or more of the claims of the '179 patent under 35 U.S.C. § 271(e)(2)(A).

83. Upon information and belief, Handa intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its 505(b)(2) NDA Product with its proposed labeling immediately and imminently upon final approval of its 505(b)(2) NDA.

84. Handa, by filing its 505(b)(2) NDA, has represented to the FDA that, upon approval, its 505(b)(2) NDA Product will have the same active ingredient or a pharmaceutically acceptable salt thereof and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®. Specifically, Handa has indicated to Novartis that its 505(b)(2) NDA Product contains the same drug in the same dosage amount as GILENYA®, and that Handa's 505(b)(2) NDA contains the bioavailability and/or bioequivalence data and information from studies of Handa's 505(b)(2) NDA Product.

85. Handa has indicated that its 505(b)(2) NDA Product is orally administered and contains 0.5 mg fingolimod.

86. FDA regulations require that Handa's 505(b)(2) NDA Product labeling contain safety information associated with its 505(b)(2) NDA Product. *See* 21 C.F.R. 201.56(a)(1) ("The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug."); 21 C.F.R. 201.57(c)(6) (requiring under "Warnings and precautions" a description of "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards [], limitations in use imposed by them [], and steps that should be taken if they occur[.]")

87. As reflected in the GILENYA® label (attached hereto as **Exhibit C**) under the heading "WARNINGS AND PRECAUTIONS" and further under the heading "Infections," FDA has required instruction that "[p]atients without a healthcare professional confirmed history of chickenpox or without documentation of a full course of vaccination against VZV should be tested for antibodies to VZV before initiating GILENYA" and furthermore that "VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with GILENYA." Upon information and belief, Handa's 505(b)(2) NDA proposed labeling contains an identical or substantially similar instruction.

88. FDA regulations require that Handa's 505(b)(2) NDA Product labeling instruct that its 505(b)(2) NDA Product be administered for approved indications at approved dosages. *See* 21 U.S.C. § 355(d) (setting forth that FDA may reject an NDA that does not contain reports showing "adequate tests by all methods reasonably applicable to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed

labeling thereof"); 21 C.F.R. § 201.57(c)(2)(iv) (requiring that "all indications listed in [the Indications and Usage] section [of the drug labeling] must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b)," where § 314.126(b) provides placebo concurrent control, dose-comparison concurrent control, and active treatment concurrent control as examples).

89. Upon information and belief, the only FDA-approved indication for fingolimod, and the only indication adequately supported by adequate tests and studies, is the same as that of Novartis's GILENYA® product and that recited in at least claim 1 of the '179 patent, specifically the treatment of relapsing-remitting multiple sclerosis.

90. Thus, upon information and belief, Handa's 505(b)(2) NDA Product labeling will disclose all elements of at least claim 1 of the '179 patent, therefore showing that use by, for example, patients and/or healthcare providers of Handa's 505(b)(2) NDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '179 patent.

91. Upon information and belief, Handa's 505(b)(2) NDA Product's proposed labeling will instruct, for example, patients and/or healthcare providers to perform all elements of at least claim 1 of the '179 patent.

92. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Handa's 505(b)(2) NDA Product would infringe one or more claims of the '179 patent.

93. Upon information and belief, use of Handa's 505(b)(2) NDA Product in accordance with and as directed by its proposed labeling would infringe one or more claims of the '179 patent.

94. Upon information and belief, Handa will have actual knowledge of the '179 patent and will actively induce infringement of the '179 patent when its 505(b)(2) NDA is approved, and will do so immediately and imminently upon final approval.

95. Upon information and belief, Handa will know that its 505(b)(2) NDA Product is especially made or adapted for use in infringing the '179 patent, and that its 505(b)(2) NDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Handa will contribute to the infringement of the '179 patent immediately and imminently upon approval of its 505(b)(2) NDA.

96. The foregoing acts by Handa constitute and/or will constitute active inducement of infringement of the '179 patent and/or contribution to the infringement by others of the '179 patent under 35 U.S.C. §§ 271(b) and (c).

97. If Handa's infringement of the '179 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT BY EACH DEFENDANT OF THE '179 PATENT UNDER 35 U.S.C. 271(b) AND (c)

98. Plaintiff incorporates each of the preceding paragraphs 1 – 97 as if fully set forth herein.

99. Upon information and belief, Handa intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its 505(b)(2) NDA Product with its proposed labeling immediately and imminently upon final approval of its 505(b)(2) NDA. Therefore a case or controversy exists between each Defendant or group of Defendants and Novartis as to infringement of the '179 patent.

100. Handa, by filing its 505(b)(2) NDA, has represented to the FDA that, upon approval, its 505(b)(2) NDA Product will have the same active ingredient or a pharmaceutically

acceptable salt thereof and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®. Specifically, Handa has indicated to Novartis that its 505(b)(2) NDA Product contains the same drug in the same dosage amount as GILENYA®, and that Handa's 505(b)(2) NDA contains the bioavailability and/or bioequivalence data and information from studies of Handa's 505(b)(2) NDA Product.

101. Handa has indicated that its 505(b)(2) NDA Product is orally administered and contains 0.5 mg fingolimod.

102. FDA regulations require that Handa's 505(b)(2) NDA Product labeling contain safety information associated with its 505(b)(2) NDA Product. *See* 21 C.F.R. 201.56(a)(1) ("The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug."); 21 C.F.R. 201.57(c)(6) (requiring under "Warnings and precautions" a description of "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards [], limitations in use imposed by them [], and steps that should be taken if they occur[.]")

103. As reflected in the GILENYA® label (attached hereto as **Exhibit C**) under the heading "WARNINGS AND PRECAUTIONS" and further under the heading "Infections," FDA has required instruction that "[p]atients without a healthcare professional confirmed history of chickenpox or without documentation of a full course of vaccination against VZV should be tested for antibodies to VZV before initiating GILENYA" and furthermore that "VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with GILENYA." Upon information and belief, Handa's 505(b)(2) NDA proposed labeling contains an identical or substantially similar instruction.

104. FDA regulations require that Handa's 505(b)(2) NDA Product labeling instruct that its 505(b)(2) NDA Product be administered for approved indications at approved dosages. *See* 21 U.S.C. § 355(d) (setting forth that FDA may reject an NDA that does not contain reports showing "adequate tests by all methods reasonably applicable to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof"); 21 C.F.R. § 201.57(c)(2)(iv) (requiring that "all indications listed in [the Indications and Usage] section [of the drug labeling] must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b)," where § 314.126(b) provides placebo concurrent control, dose-comparison concurrent control, and active treatment concurrent control as examples).

105. Upon information and belief, the only FDA-approved indication for fingolimod, and the only indication adequately supported by adequate tests and studies, is the same as that of Novartis's GILENYA® product and that recited in at least claim 1 of the '179 patent, specifically the treatment of relapsing-remitting multiple sclerosis.

106. Thus, upon information and belief, Handa's 505(b)(2) NDA Product labeling will disclose all elements of at least claim 1 of the '179 patent, therefore showing that use by, for example, patients and/or healthcare providers of Handa's 505(b)(2) NDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '179 patent.

107. Upon information and belief, Handa's 505(b)(2) NDA Product's proposed labeling will instruct, for example, patients and/or healthcare providers to perform all elements of at least claim 1 of the '179 patent.

108. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Handa's 505(b)(2) NDA Product would infringe one or more claims of the '179 patent.

109. Upon information and belief, use of Handa's 505(b)(2) NDA Product in accordance with and as directed by its proposed labeling would infringe one or more claims of the '179 patent.

110. Upon information and belief, Handa will have actual knowledge of the '179 patent and will actively induce infringement of the '179 patent when its 505(b)(2) NDA is approved, and will do so immediately and imminently upon final approval.

111. Upon information and belief, Handa will know that its 505(b)(2) NDA Product is especially made or adapted for use in infringing the '179 patent, and that its 505(b)(2) NDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Handa will contribute to the infringement of the '179 patent immediately and imminently upon approval of its 505(b)(2) NDA.

112. The foregoing acts by Handa constitute and/or will constitute active inducement of infringement of the '179 patent and/or contribution to the infringement by others of the '179 patent under 35 U.S.C. §§ 271(b) and (c).

113. If Handa's infringement of the '179 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A declaration that Handa's imminent making, using, offering to sell, or selling in the United States, or importing into the United States, or inducing or contributing to the same, of its ANDA Product will infringe the '405 patent.

2. A judgment that one or more claims of the '405 patent is not invalid, is not unenforceable, and is infringed Handa's 505(b)(2) NDA submission, and that Handa's making, using, offering to sell, or selling in the United States, or importing into the United States of its 505(b)(2) NDA Product will infringe the '405 patent.

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Handa's 505(b)(2) NDA shall be a date not earlier than the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. An order enjoining Handa, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or in concert with Handa, from making, using, offering to sell, or selling in the United States, or importing into the United States its 505(b)(2) NDA Product, until after the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Damages, including monetary and other relief, to Novartis if Handa engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its 505(b)(2) NDA Product, prior to the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

6. A declaration that Handa's imminent making, using, offering to sell, or selling in the United States, or importing into the United States, or inducing or contributing to the same, of its ANDA Product will infringe the '179 patent.

7. A judgment that one or more claims of the ’179 patent is not invalid, is not unenforceable, and is infringed by Handa’s 505(b)(2) NDA submission, and that Handa’s making, using, offering to sell, or selling in the United States, or importing into the United States of its 505(b)(2) NDA Product will infringe the ’179 patent.

8. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Handa’s 505(b)(2) NDA shall be a date not earlier than the expiration date of the ’179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

9. An order enjoining Handa, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or in concert with Handa, from making, using, offering to sell, or selling in the United States, or importing into the United States its 505(b)(2) NDA Product, until after the expiration date of the ’179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

10. Damages, including monetary and other relief, to Novartis if Handa engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its 505(b)(2) NDA Product, prior to the expiration date of the ’179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

11. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: May 4, 2021

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