IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. ALVOGEN, INC. AND ALMAJECT, INC., Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Alvogen, Inc. and Almaject, Inc. (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,525,057 ("the '057 patent"), 10,980,803 ("the '803 patent"), 11,154,553 ("the '553 patent"), 11,344,547 ("the '547 patent"), 11,400,087 ("the '087 patent") and 11,648,347 ("the '347 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 216913 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and/or sell aripiprazole vials, 300 mg and 400 mg ("Defendants' generic products"), which are generic versions of Otsuka's ABILIFY

MAINTENA® (aripiprazole), for the treatment of schizophrenia in adults, and maintenance monotherapy treatment of bipolar I disorder in adults before the expiration of the patents in suit.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '057, the '803, the '553, the '547, the '087 and the '347 patents.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Alvogen, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 44 Whippany Rd. Suite 300, Morristown, NJ 07960.

6. Upon information and belief, Alvogen, Inc. is a wholly-owned subsidiary of Alvogen Pharma US, Inc.

7. Upon information and belief, Almaject, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 44 Whippany Rd. Suite 300, Morristown, NJ 07960.

8. Upon information and belief, Almaject, Inc. is a wholly-owned subsidiary of Alvogen, Inc.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Alvogen, Inc. Alvogen, Inc. is

incorporated in the State of Delaware. Additionally, upon information and belief, Alvogen, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Alvogen, Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Alvogen, Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

11. This Court also has personal jurisdiction over Alvogen, Inc. because it has previously been sued in this judicial district and has not challenged personal jurisdiction and/or it has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this judicial district. *See, e.g.*, *Novo Nordisk Inc. et al. v. Alvogen, Inc.*, C.A. No. 22-299-CFC (D. Del.); *BioDelivery Scis. Int'l, Inc. et al. v. Alvogen PB Rsch. & Dev. LLC, et al.*, C.A. No. 18-1395-CFC (D. Del.); *Noven Pharms., Inc. v. Alvogen Pine Brook LLC, et al.*, C.A. No. 17-1429-LPS (D. Del.).

12. Upon information and belief, Alvogen, Inc., either directly or indirectly, currently sells significant quantities of generic drug products in the United States and in this judicial district. Alvogen, Inc.'s website states it is a "US-based company focused on developing, in-licensing, manufacturing and marketing pharmaceutical products." https://www.alvogen.com/company (accessed Feb. 13, 2025). Alvogen, Inc.'s website further states under the product heading "Generics": "An experienced team of professionals from the generics and brand industry has built a strong profitable base and infrastructure for our generic and brand business in the U.S. Product formulations manufactured and sold by Alvogen include solid oral dose, tab-in-tab tablets, modified release tablets, soft gelatin capsules, powder capsules, bead capsules, oral suspension,

oral thin film, transdermals, creams, ointments, and injectables—both pen and vial." https://www.alvogen.com/products (accessed Feb. 13, 2025).

13. Upon information and belief, Alvogen, Inc. states that it "grew rapidly into a world-leading generics organization, producing hundreds of products sold across four continents." https://www.alvogen.com/company/meet-the-chairman (accessed Feb. 13, 2025).

14. Upon information and belief, Alvogen, Inc. has an active pharmacy wholesale license in the State of Delaware with the license number A4-0001942.

15. This Court has personal jurisdiction over Almaject, Inc. Almaject, Inc. is incorporated in the State of Delaware. Additionally, upon information and belief, Almaject, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Almaject, Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Almaject, Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

16. Upon information and belief, Almaject, Inc. is a generic pharmaceutical company that, in coordination with or at the direction of Alvogen, Inc., develops, manufactures, markets, imports and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States. Almaject, Inc.'s website states: "Almaject® Inc. is a wholly owned subsidiary of Alvogen, specializing in the commercialization of generic injectable pharmaceuticals for the acute and alternate site healthcare markets in the US." https://www.almaject.com/ (accessed Feb. 13, 2025); *see also* https://www.alvogen.com/products (accessed Feb. 13, 2025).

17. Upon information and belief, Almaject, Inc., either directly or indirectly, currently

sells significant quantities of generic drug products in the United States and in this judicial district. Almaject, Inc.'s website states: "Almaject® is focused on the development, acquisition, and commercialization of injectable generic pharmaceutical products. The current portfolio of injectables covers a broad range of therapeutic areas." https://www.almaject.com/company-overview (accessed Feb. 13, 2025).

18. Upon information and belief, Almaject, Inc. regularly imports drug products into the United States. https://datadashboard.fda.gov/ora/cd/impentry-table.htm (searching manufacturer legal name: "Almaject Inc." yields 22 search results between May. 8, 2022 and Nov. 14, 2024) (last searched Feb. 13, 2025).

19. Upon information and belief, Rama Yarasani is presently Alvogen, Inc. and Almaject, Inc.'s Chief Scientific Officer, and is "responsible for all aspects of Generics and Brand R&D, including Biopharmaceutics, Clinical Pharmacology, Project Management, product transfers and commercial validation at all internal and external sites." https://www.alvogen.com/team/rama-yarasani (accessed Feb. 13, 2025); *see also* https://www.almaject.com/team/rama-yarasani (accessed Feb. 13, 2025) ("Rama Yarasani joined Almaject in September 2018 and is responsible for management of all aspects of CMS, Clinical Pharmacology, Regulatory Affairs, Project Management, Commercial Validation and Product Transfers.").

20. Upon information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district and including for Defendants' generic products that are the subject of ANDA No. 216913.

21. Alvogen, Inc.'s website states that Alvogen's companies include: Alvogen generic business, Almatica brand products, Almaject injectables and Norwich US-based manufacturing. https://www.alvogen.com/company (accessed Feb. 13, 2025).

22. Upon information and belief, Alvogen, Inc. describes itself as "a major force in difficult-to-make generics in the US, including its injectables division Almaject." https://www.alvogen.com/company/meet-the-chairman (accessed Feb. 13, 2025).

23. Defendants' ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' generic products in this judicial district.

24. Defendants have taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Defendants intend to direct sales of their generic drugs in this judicial district, among other places, once Defendants receive the requested FDA approval to market their generic products. Upon information and belief, Defendants will engage in marketing of their proposed generic products in Delaware upon approval of their ANDA.

25. Upon information and belief, Defendants have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 216913 and intend to benefit from the ANDA.

26. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Alvogen, Inc. is incorporated in Delaware.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b),

because Almaject, Inc. is incorporated in Delaware.

FACTUAL BACKGROUND

The NDA

28. Otsuka is the holder of New Drug Application ("NDA") No. 202971 for ABILIFY MAINTENA® (aripiprazole for extended-release injectable suspension) in strengths of 300 mg and 400 mg vials and pre-filled syringes.

29. The FDA approved NDA No. 202971 on February 28, 2013.

30. ABILIFY MAINTENA® is a prescription drug approved for the treatment of schizophrenia and maintenance monotherapy treatment of bipolar I disorder. Aripiprazole is the active ingredient in ABILIFY MAINTENA®.

The Patents in Suit

31. The United States Patent and Trademark Office ("PTO") issued the '057 patent on January 7, 2020, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '057 patent is attached as Exhibit A.

32. Otsuka owns the '057 patent through assignment as recorded by the PTO at Reel 033071, Frame 0910.

33. The '057 patent expires on March 8, 2034, by virtue of 165 days of patent term adjustment granted to the '057 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit B.

34. The '057 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 202971 for ABILIFY MAINTENA®.

35. The PTO issued the '803 patent on April 20, 2021, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '803 patent is attached as Exhibit C.

36. Otsuka owns the '803 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

37. The '803 patent expires on September 24, 2033.

38. The '803 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

39. The PTO issued the '553 patent on October 26, 2021, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '553 patent is attached as Exhibit D.

40. Otsuka owns the '553 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

41. The '553 patent expires on September 24, 2033.

42. The '553 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

43. The PTO issued the '547 patent on May 31, 2022, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '547 patent is attached as Exhibit E.

44. Otsuka owns the '547 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

45. The '547 patent expires on September 24, 2033.

46. The ’547 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

47. The PTO issued the ’087 patent on August 2, 2022, titled “Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function.” A true and correct copy of the ’087 patent is attached as Exhibit F.

48. Otsuka owns the ’087 patent through assignment as recorded by the PTO for the ’057 patent at Reel 033071, Frame 0910.

49. The ’087 patent expires on September 24, 2033.

50. The ’087 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

51. The PTO issued the ’347 patent on May 16, 2023, titled “Medical Device Containing a Cake Composition Comprising Aripiprazole as an Active Ingredient, and a Cake Composition Comprising Aripiprazole as an Active Ingredient.” A true and correct copy of the ’347 patent is attached as Exhibit G.

52. Otsuka owns the ’347 patent through assignment as recorded by the PTO at Reel 030905, Frame 0822.

53. The ’347 patent expires on April 6, 2034, by virtue of 257 days of patent term adjustment granted to the ’347 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit H.

54. The ’347 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

The ANDA

55. Upon information and belief, Defendants submitted ANDA No. 216913 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the manufacture, use, and/or sale in the United States of aripiprazole vials, 300 mg and 400 mg (defined above as "Defendants' generic products"), which is a generic version of Otsuka's ABILIFY MAINTENA® (aripiprazole), for the treatment of schizophrenia in adults, and maintenance monotherapy treatment of bipolar I disorder in adults.

56. Upon information and belief, ANDA No. 216913 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents in suit are invalid, unenforceable and/or would not be infringed by Defendants' generic products.

57. Otsuka received a letter sent by Defendants, dated January 3, 2025, purporting to be a "Notification Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act for ANDA No. 216913," ("Defendants' Notice Letter"). Defendants' Notice Letter identified Defendants' ANDA as "ANDA No. 216913." Defendants' Notice Letter included an enclosure purporting to be a "Detailed Factual and Legal Bases for Alvogen's Certification That It Will Not Infringe Any Valid or Enforceable Claim of [the patents in suit]."

58. Defendants' Notice Letter states that Defendants had filed ANDA No. 216913 seeking "to obtain approval to engage in the commercial manufacture, use, or sale" of Defendants' generic products before the expiration of the patents in suit.

59. Plaintiffs commenced this action within 45 days of receiving Defendants' Notice Letter.

COUNT I

(INFRINGEMENT OF THE '057 PATENT)

60. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

61. Upon information and belief, Defendants filed ANDA No. 216913 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '057 patent.

62. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '057 patent are invalid, unenforceable and/or not infringed.

63. Upon information and belief, in their ANDA No. 216913, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

64. Defendants have actual knowledge of the '057 patent, as evidenced by Defendants' Notice Letter.

65. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '057 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216913, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '057 patent.

66. Upon information and belief, if ANDA No. 216913 is approved, Defendants will infringe one or more claims of the '057 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 216913 shall be no earlier than the expiration of the '057 patent and any additional periods of exclusivity.

67. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 216913, and therefore will infringe at least one claim of the '057 patent.

68. Upon information and belief, Defendants have knowledge of the '057 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '057 patent, either literally or under the doctrine of equivalents.

69. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '057 patent.

70. Upon information and belief, if ANDA No. 216913 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

71. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216913 complained of herein were done by and for the benefit of Defendants.

72. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

73. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '803 PATENT)

74. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

75. Upon information and belief, Defendants filed ANDA No. 216913 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '803 patent.

76. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '803 patent are invalid, unenforceable and/or not infringed.

77. Upon information and belief, Defendants concede infringement of at least one claim of the '803 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement for multiple claims.

78. Upon information and belief, in their ANDA No. 216913, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

79. Defendants have actual knowledge of the '803 patent, as evidenced by Defendants' Notice Letter.

80. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '803 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216913, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '803 patent.

81. Upon information and belief, if ANDA No. 216913 is approved, Defendants will infringe one or more claims of the '803 patent under § 271(a), either literally or under the doctrine

of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216913 shall be no earlier than the expiration of the '803 patent and any additional periods of exclusivity.

82. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 216913, and therefore will infringe at least one claim of the '803 patent.

83. Upon information and belief, Defendants have knowledge of the '803 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '803 patent, either literally or under the doctrine of equivalents.

84. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '803 patent.

85. Upon information and belief, if ANDA No. 216913 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

86. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216913 complained of herein were done by and for the benefit of Defendants.

87. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

88. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '553 PATENT)

89. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

90. Upon information and belief, Defendants filed ANDA No. 216913 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '553 patent.

91. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '553 patent are invalid, unenforceable and/or not infringed.

92. Upon information and belief, in their ANDA No. 216913, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

93. Defendants have actual knowledge of the '553 patent, as evidenced by Defendants' Notice Letter.

94. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '553 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216913, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '553 patent.

95. Upon information and belief, if ANDA No. 216913 is approved, Defendants will infringe one or more claims of the '553 patent under § 271(a), either literally or under the doctrine

of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216913 shall be no earlier than the expiration of the '553 patent and any additional periods of exclusivity.

96. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 216913, and therefore will infringe at least one claim of the '553 patent.

97. Upon information and belief, Defendants have knowledge of the '553 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '553 patent, either literally or under the doctrine of equivalents.

98. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '553 patent.

99. Upon information and belief, if ANDA No. 216913 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

100. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216913 complained of herein were done by and for the benefit of Defendants.

101. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

102. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '547 PATENT)

103. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

104. Upon information and belief, Defendants filed ANDA No. 216913 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '547 patent.

105. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '547 patent are invalid, unenforceable and/or not infringed.

106. Upon information and belief, in their ANDA No. 216913, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

107. Defendants have actual knowledge of the '547 patent, as evidenced by Defendants' Notice Letter.

108. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '547 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216913, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '547 patent.

109. Upon information and belief, if ANDA No. 216913 is approved, Defendants will infringe one or more claims of the '547 patent under § 271(a), either literally or under the doctrine

of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216913 shall be no earlier than the expiration of the '547 patent and any additional periods of exclusivity.

110. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 216913, and therefore will infringe at least one claim of the '547 patent.

111. Upon information and belief, Defendants have knowledge of the '547 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '547 patent, either literally or under the doctrine of equivalents.

112. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '547 patent.

113. Upon information and belief, if ANDA No. 216913 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

114. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216913 complained of herein were done by and for the benefit of Defendants.

115. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

116. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '087 PATENT)

117. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

118. Upon information and belief, Defendants filed ANDA No. 216913 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '087 patent.

119. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '087 patent are invalid, unenforceable and/or not infringed.

120. Upon information and belief, Defendants concede infringement of at least one claim of the '087 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement for multiple claims.

121. Upon information and belief, in their ANDA No. 216913, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

122. Defendants have actual knowledge of the '087 patent, as evidenced by Defendants' Notice Letter.

123. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '087 patent by submitting, or causing to be submitted, to the

FDA ANDA No. 216913, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '087 patent.

124. Upon information and belief, if ANDA No. 216913 is approved, Defendants will infringe one or more claims of the '087 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216913 shall be no earlier than the expiration of the '087 patent and any additional periods of exclusivity.

125. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 216913, and therefore will infringe at least one claim of the '087 patent.

126. Upon information and belief, Defendants have knowledge of the '087 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '087 patent, either literally or under the doctrine of equivalents.

127. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '087 patent.

128. Upon information and belief, if ANDA No. 216913 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

129. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216913 complained of herein were done by and for the benefit of Defendants.

130. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

131. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '347 PATENT)

132. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

133. Upon information and belief, Defendants filed ANDA No. 216913 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '347 patent.

134. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '347 patent are invalid, unenforceable and/or not infringed.

135. Upon information and belief, in their ANDA No. 216913, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

136. Defendants have actual knowledge of the '347 patent, as evidenced by Defendants' Notice Letter.

137. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '347 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216913, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '347 patent.

138. Upon information and belief, if ANDA No. 216913 is approved, Defendants will infringe one or more claims of the '347 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216913 shall be no earlier than the expiration of the '347 patent and any additional periods of exclusivity.

139. Upon information and belief, if ANDA No. 216913 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

140. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216913 complained of herein were done by and for the benefit of Defendants.

141. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

142. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '057 patent through Defendants' submission of ANDA No.

216913 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '057 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '057 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '057 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '057 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '057 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '057 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '803 patent through Defendants' submission of ANDA No. 216913 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '803 patent;

G. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '803 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '803 patent under 35 U.S.C. § 271(a), (b) and/or (c);

H. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '803 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

I. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '803 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

J. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '803 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '553 patent through Defendants' submission of ANDA No. 216913 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '553 patent;

L. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the

expiration of the '553 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '553 patent under 35 U.S.C. § 271(a), (b) and/or (c);

M. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '553 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

N. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '553 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

O. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '553 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

P. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '547 patent through Defendants' submission of ANDA No. 216913 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '547 patent;

Q. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '547 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '547 patent under 35 U.S.C. § 271(a), (b) and/or (c);

R. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '547 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

S. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '547 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

T. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '547 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

U. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '087 patent through Defendants' submission of ANDA No. 216913 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '087 patent;

V. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '087 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '087 patent under 35 U.S.C. § 271(a), (b) and/or (c);

W. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '087 patent and any additional

periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

X. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '087 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Y. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '087 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Z. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '347 patent through Defendants' submission of ANDA No. 216913 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '347 patent;

AA. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '347 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '347 patent under 35 U.S.C. § 271(a), (b) and/or (c);

BB. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '347 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

CC. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '347 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

DD. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '347 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

EE. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

FF. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

GG. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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