IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED AND SUN PHARMACEUTICAL INDUSTRIES, 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 Sun Pharmaceutical Industries Limited ("Sun Limited") and Sun Pharmaceutical Industries, Inc. ("Sun 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 an Abbreviated New Drug Application ("ANDA") No. 216818 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 for extended-release injectable suspension, 400 mg/vial ("Defendants' generic product"), which is a generic version of Otsuka's ABILIFY MAINTENA® (aripiprazole), 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, Sun Limited is a corporation organized and existing under the laws of India, with a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India, 400063.

6. Upon information and belief, Sun Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2 Independence Way, Princeton, New Jersey, 08540.

7. Upon information and belief, Sun Inc. is a wholly-owned subsidiary and United States agent of Sun Limited.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Sun Limited. Upon information and

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

10. This Court also has personal jurisdiction over Sun Limited because it has previously been sued in this judicial district and has not challeged personal jurisdiction and/or it has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this judicial district. *See, e.g.*, *Allergan Holdings Unlimited Co., et al v. Sun Pharm. Indus. Ltd.*, C.A. No. 23-795-RGA; *Vertex Pharms. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 23-666-RGA; *Boehringer Ingelheim Pharms. Inc., et al. v. Sun Pharm. Indus. Ltd. et al,* C.A. No. 21-1573-CFC; *Millennium Pharms. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-289-CFC.

11. Upon information and belief, Sun Limited, either directly or indirectly, currently sells significant quantities of generic drug products in the United States and in this judicial district. Sun Limited's website states: "Over the last two decades, Sun Pharma has established itself as a leading player in the generics market in the U.S. We are a leading specialty generics pharmaceutical company in the U.S. and are ranked 2nd by prescriptions in the U.S. dermatology market. We are rapidly ramping up our presence in the specialty branded market, with dermatology, ophthalmology and oncology as key target segments. Our U.S. business makes up 30% of our global revenue." https://sunpharma.com/usa/ (accessed Jul. 5, 2024).

12. Sun Limited's website states: "Our U.S. headquarters is in Princeton, New Jersey, with distribution, manufacturing and R&D teams at multiple locations across the country."

https://sunpharma.com/usa/ (accessed Jul. 5, 2024).

13. Sun Limited's annual report states that as of "FY23" Sun Limited had cumulatively filed 616 ANDAs and that 519 of those ANDAs had been approved. https://sunpharma.com/wp-content/uploads/2023/07/SPIL-AR2022-23-Complete-Annual-Report.pdf (at Graph 18) (accessed Jul. 5, 2024).

14. Upon information and belief, Sun Limited is the holder of FDA Drug Master File No. 19949 for aripiprazole and FDA Drug Master File No. 36774 for aripiprazole USP.

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

16. Upon information and belief, Sun Inc. is a generic pharmaceutical company that, in coordination with or at the direction of Sun Limited, develops, manufactures, markets, imports and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States. Upon information and belief, Sun Inc. is the United States agent for Defendants' generic product that is the subject of ANDA No. 216818.

17. 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 product that is the subject of ANDA No. 216818.

18. 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 product in this judicial district.

19. 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.

20. 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. 216818 and intend to benefit from the ANDA.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Sun Limited is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

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

FACTUAL BACKGROUND

The NDA

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

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

25. 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

26. 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.

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

28. 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.

29. 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®.

30. 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.

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

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

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

34. 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.

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

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

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

38. 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.

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

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

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

42. 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.

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

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

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

46. 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.

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

48. 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.

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

The ANDA

50. Upon information and belief, Defendants submitted ANDA No. 216818 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 for extended-release injectable suspension, 400 mg/vial (defined above as "Defendants' generic product"), which is a generic version of Otsuka's ABILIFY MAINTENA® (aripiprazole).

51. Upon information and belief, ANDA No. 216818 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 product.

52. Otsuka received a letter sent by Defendants, dated May 23, 2024, purporting to be a "Notice of Paragraph IV Certification" for an ANDA, ("Defendants' Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. §§ 314.94-314.95. Defendants' Notice Letter identified Defendants' ANDA as "ANDA No. 216818." Defendants' Notice Letter included Exhibit A purporting to be a "Detailed Statement of the Factual and Legal Bases for Sun's Paragraph IV Certifications That [the patents in suit] Are Invalid, Unenforceable, and/or Will Not Be Infringed." Page 1 of Exhibit A identifies "Sun Pharmaceutical Industries, Inc." as the U.S. agent for Sun Limited. Similarly, the signature block on page 6 of Defendants' Notice Letter identifies counsel for "Sun Pharmaceutical Industries, Inc."

53. Defendants' Notice Letter at page 1, however, identified "Sun Pharmaceutical Industries Inc." without the commas as in the other two instances as "U.S. Agent for applicant Sun Pharmaceuticals Industries Limited."

54. Upon information and belief, the "Sun Pharmaceutical Industries Inc." identified on page 1 of Defendants' Notice Letter without the comma is the same entity as "Sun Pharmaceutical Industries, Inc." (containing a comma) which is identified in the signature block on page 6 of Defendants' Notice Letter and on page 1 of Exhibit A of Defendants' Notice Letter. Sun Pharmaceutical Industries, Inc. was incorporated in Delaware on March 11, 2020, under File Number 7893212.

55. On page 1 of Exhibit A of Defendants' Notice Letter, "Sun Pharmaceutical Industries Limited" is identified. Upon information and belief, the "Sun Pharmaceuticals Industries Limited" identified on page 1 of Defendants' Notice Letter is the same entity as "Sun Pharmaceutical Industries Limited" (containing singular "Pharmaceutical") that is identified on page 1 of Exhibit A of Defendants' Notice Letter. Sun Pharmaceutical Industries Limited was incorporated in India on March 1, 1993, under Registration Number 019050 and having CIN L24230GJ1993PLC019050.

56. Defendants' Notice Letter purports to be a "Notice of Paragraph IV Certification" for an ANDA pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. §§ 314.94-314.95. Defendants' Notice Letter identified Defendants' ANDA as "ANDA No. 216818" and states that Defendants had filed ANDA No. 216818 seeking "to obtain approval to engage in the commercial manufacture, use, and sale" of Defendants' generic product before the expiration of the patents in suit.

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

COUNT I

(INFRINGEMENT OF THE '057 PATENT)

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

59. Upon information and belief, Defendants filed ANDA No. 216818 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States before the expiration of the '057 patent.

60. 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.

61. Upon information and belief, Defendants admit infringement of at least one claim of the '057 patent because Defendants' Notice Letter did not provide non-infringement allegations beyond asserting alleged invalidity for one or more claims of the '057 patent.

62. Upon information and belief, in their ANDA No. 216818, Defendants have represented to the FDA that Defendants' generic product is pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

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

64. 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. 216818, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '057 patent.

65. Upon information and belief, if ANDA No. 216818 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 product, 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. 216818 shall be no earlier than the expiration of the '057 patent and any additional periods of exclusivity.

66. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic product for which approval is sought in ANDA No. 216818, and therefore will infringe at least one claim of the '057 patent.

67. Upon information and belief, Defendants have knowledge of the '057 patent and, by their proposed package insert for Defendants' generic product, 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.

68. 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 product according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '057 patent.

69. Upon information and belief, if ANDA No. 216818 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States.

70. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216818 complained of herein were done by and for the benefit of Defendants.

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

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

COUNT II

(INFRINGEMENT OF THE '803 PATENT)

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

74. Upon information and belief, Defendants filed ANDA No. 216818 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States before the expiration of the '803 patent.

75. 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.

76. Upon information and belief, Defendants admit infringement of at least one claim of the '803 patent because Defendants' Notice Letter did not provide non-infringement allegations beyond asserting alleged invalidity for one or more claims of the '803 patent.

77. Upon information and belief, in their ANDA No. 216818, Defendants have represented to the FDA that Defendants' generic product is pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

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

79. 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. 216818, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '803 patent.

80. Upon information and belief, if ANDA No. 216818 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 product, 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. 216818 shall be no earlier than the expiration of the '803 patent and any additional periods of exclusivity.

81. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic product for which approval is sought in ANDA No. 216818, and therefore will infringe at least one claim of the '803 patent.

82. Upon information and belief, Defendants have knowledge of the '803 patent and, by their proposed package insert for Defendants' generic product, 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.

83. 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 product according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '803 patent.

84. Upon information and belief, if ANDA No. 216818 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States.

85. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216818 complained of herein were done by and for the benefit of Defendants.

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

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

COUNT III

(INFRINGEMENT OF THE '553 PATENT)

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

89. Upon information and belief, Defendants filed ANDA No. 216818 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States before the expiration of the '553 patent.

90. 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.

91. Upon information and belief, Defendants admit infringement of at least one claim of the '553 patent because Defendants' Notice Letter did not provide non-infringement allegations beyond asserting alleged invalidity for one or more claims of the '553 patent.

92. Upon information and belief, in their ANDA No. 216818, Defendants have represented to the FDA that Defendants' generic product is 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. 216818, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '553 patent.

95. Upon information and belief, if ANDA No. 216818 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 product, 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. 216818 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 product for which approval is sought in ANDA No. 216818, 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 product, 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 product 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. 216818 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States.

100. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216818 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. 216818 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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, Defendants admit infringement of at least one claim of the '547 patent because Defendants' Notice Letter did not provide non-infringement allegations beyond asserting alleged invalidity for one or more claims of the '547 patent.

107. Upon information and belief, in their ANDA No. 216818, Defendants have represented to the FDA that Defendants' generic product is pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

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

109. 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. 216818, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '547 patent.

110. Upon information and belief, if ANDA No. 216818 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 product, 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. 216818 shall be no earlier than the expiration of the '547 patent and any additional periods of exclusivity.

111. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic product for which approval is sought in ANDA No. 216818, and therefore will infringe at least one claim of the '547 patent.

112. Upon information and belief, Defendants have knowledge of the '547 patent and, by their proposed package insert for Defendants' generic product, 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.

113. 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 product according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '547 patent.

114. Upon information and belief, if ANDA No. 216818 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States.

115. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216818 complained of herein were done by and for the benefit of Defendants.

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

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

COUNT V

(INFRINGEMENT OF THE '087 PATENT)

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

119. Upon information and belief, Defendants filed ANDA No. 216818 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States before the expiration of the '087 patent.

120. 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.

121. Upon information and belief, Defendants admit infringement of at least one claim of the '087 patent because Defendants' Notice Letter did not provide non-infringement allegations beyond asserting alleged invalidity for one or more claims of the '087 patent.

122. Upon information and belief, in their ANDA No. 216818, Defendants have represented to the FDA that Defendants' generic product is pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

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

124. 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. 216818, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '087 patent.

125. Upon information and belief, if ANDA No. 216818 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 product, 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. 216818 shall be no earlier than the expiration of the '087 patent and any additional periods of exclusivity.

126. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic product for which approval is sought in ANDA No. 216818, and therefore will infringe at least one claim of the '087 patent.

127. Upon information and belief, Defendants have knowledge of the '087 patent and, by their proposed package insert for Defendants' generic product, 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.

128. 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 product according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '087 patent.

129. Upon information and belief, if ANDA No. 216818 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States.

130. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216818 complained of herein were done by and for the benefit of Defendants.

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

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

COUNT VI

(INFRINGEMENT OF THE '347 PATENT)

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

134. Upon information and belief, Defendants filed ANDA No. 216818 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States before the expiration of the '347 patent.

135. 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.

136. Upon information and belief, in their ANDA No. 216818, Defendants have represented to the FDA that Defendants' generic product is pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

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

138. 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. 216818, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '347 patent.

139. Upon information and belief, if ANDA No. 216818 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 product, 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. 216818 shall be no earlier than the expiration of the '347 patent and any additional periods of exclusivity.

140. Upon information and belief, if ANDA No. 216818 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic product in the United States.

141. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216818 complained of herein were done by and for the benefit of Defendants.

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

143. 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. 216818 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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 product 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 product 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 product within the United States, or importing Defendants'

generic product 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. 216818 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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 product 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 product 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 product within the United States, or importing Defendants' generic product 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. 216818 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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 product 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 product 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 product within the United States, or importing Defendants' generic product 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. 216818 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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 product 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 product 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 product within the United States, or importing Defendants' generic product 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. 216818 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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 product 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 product 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 product within the United States, or importing Defendants' generic product 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.

216818 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic product 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 product 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 product 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 product within the United States, or importing Defendants' generic product 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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