IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S,	)	
Plaintiffs,	)	C.A. No. 24-789-JLH
v.	)	
SUN PHARMACEUTICAL INDUSTRIES LIMITED AND SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

DEFENDANTS' ANSWER,
DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively, "Sun" or "Defendants") by their undersigned attorneys, answer and respond to the Complaint of Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"):

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.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sun admits that Plaintiffs purport to bring this action under the Patent Laws of the United States. Sun admits that Sun Pharmaceutical Industries Ltd. is

the owner of ANDA No. 216818 and seeks FDA approval of ANDA No. 216818. Sun denies any remaining allegations set forth in paragraph 1.

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.

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 2 and, therefore, denies those allegations.

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.

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 3 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 4 and, therefore, denies those allegations.

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.

ANSWER: Sun admits that Sun Pharmaceutical Industries Ltd. ("SPIL") is a corporation organized and existing under the laws of India, having its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063. Sun denies any remaining allegations set forth in paragraph 5.

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.

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. ("SPI") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2 Independence Way, Princeton, New Jersey, 08540. Sun denies any remaining allegations set forth in paragraph 6.

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

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. is indirectly wholly owned by Sun Pharmaceutical Industries Ltd. Sun denies any remaining allegations set forth in paragraph 7.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required.

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.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPIL does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 9.

10. This Court also has personal jurisdiction over Sun Limited because it has previously been sued in this judicial district and has not challenged [sic] 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.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPIL does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 10.

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).

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPIL does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 11.

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).

ANSWER: SPIL admits the website listed provides: "Our U.S. headquarters is in Princeton, New Jersey, with distribution, manufacturing and R&D teams at multiple locations across the country." Sun denies any remaining allegations set forth in paragraph 12.

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).

ANSWER: SPIL admits its annual report states that as of "FY23" 616 ANDAs had been filed and that 519 of those ANDAs had been approved. Sun denies any remaining allegations set forth in paragraph 13.

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.

ANSWER: SPIL admits it is the holder of FDA Drug Master File No. 19949 for aripiprazole and FDA Drug Master File No. 36774 for aripiprazole USP. Sun denies any remaining allegations set forth in paragraph 14.

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.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPI does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 15.

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.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPI does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 16.

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.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Sun do not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 17.

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.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Sun do not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 18.

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.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, Sun do not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 19.

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.

ANSWER: Denied.

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.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sun admits SPIL is a foreign corporation. Sun denies any remaining allegations set forth in paragraph 21.

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

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sun admits SPI is a corporation organized and existing under the laws of the State of Delaware. Sun denies any remaining allegations set forth in paragraph 22.

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.

ANSWER: Sun admits that the products that are the subject of NDA No. 202971 are marketed under the trade name ABILIFY MAINTENA®. Sun admits that Otsuka is indicated in the records of the FDA as the holder of NDA No. 202971 for an injectable drug product containing, *inter alia*, 400 mg of the active pharmaceutical ingredient, aripiprazole. Sun lacks sufficient knowledge of information to form a belief as to the truth of the remaining allegations in paragraph 23 and, therefore, denies those allegations.

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

ANSWER: Sun admits that February 28, 2013 is indicated in the public records of the FDA as the approval date. Sun denies any remaining allegations set forth in paragraph 24.

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®.

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 25 and, therefore, denies those allegations.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '057 patent to the Complaint as Exhibit A. Sun admits that the '057 patent states on its face that it was issued January 7, 2020 and is titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 26 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 27 and, therefore, denies those allegations.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the patent term adjustment to the Complaint as Exhibit B. Sun admits that the patent term adjustment states on its face that the Patent Term Adjustment is 165 day(s). Sun lacks sufficient knowledge or information

to form a belief as to the remaining allegations in paragraph 28 and, therefore, denies those allegations.

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®.

ANSWER: Paragraph 29 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '057 patent is currently listed in the FDA's online version of the Orange Book in connection with NDA No. 202971. Sun denies the remaining allegations in paragraph 29.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '803 patent to the Complaint as Exhibit C. Sun admits that the '803 patent states on its face that it was issued April 20, 2021 and is titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 30 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 31 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 32 and, therefore, denies those allegations.

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

ANSWER: Paragraph 33 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '803 patent is currently listed in the FDA's online version of the Orange Book in connection with NDA No. 202971. Sun denies the remaining allegations in paragraph 33.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '553 patent to the Complaint as Exhibit D. Sun admits that the '553 patent states on its face that it was issued October 26, 2021 and is titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 34 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 35 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 36 and, therefore, denies those allegations.

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

ANSWER: Paragraph 37 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '553 patent is currently listed in the FDA's online version of the Orange Book in connection with NDA No. 202971. Sun denies the remaining allegations in paragraph 37.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '547 patent to the Complaint as Exhibit E. Sun admits that the '547 patent states on its face that it was issued May 31, 2022 and is titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 38 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 39 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 40 and, therefore, denies those allegations.

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

ANSWER: Paragraph 41 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '547 patent is currently listed in the FDA's online version of the Orange Book in connection with NDA No. 202971. Sun denies the remaining allegations in paragraph 41.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '087 patent to the Complaint as Exhibit F. Sun admits that the '087 patent states on its face that it was issued August 2, 2022 and is titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or

CYP3A4 Enzyme Function." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 42 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 43 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 44 and, therefore, denies those allegations.

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

ANSWER: Paragraph 45 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '087 patent is currently listed in the FDA's online version of the Orange Book in connection with NDA No. 202971. Sun denies the remaining allegations in paragraph 45.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '347 patent to the Complaint as Exhibit G. Sun admits that the '347 patent states on its face that it was issued May 16, 2023 and is titled "Medical Device Containing a Cake Composition Comprising Aripiprazole as an Active Ingredient, and a Cake Composition Comprising Aripiprazole as an Active Ingredient." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 46 and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 47 and, therefore, denies those allegations.

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.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the patent term adjustment to the Complaint as Exhibit H. Sun admits that the patent term adjustment states on its face that the Patent Term Adjustment is 257 day(s). Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 48 and, therefore, denies those allegations.

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

ANSWER: Paragraph 49 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '347 patent is currently listed in the FDA's online version of the Orange Book in connection with NDA No. 202971. Sun denies the remaining allegations in paragraph 49.

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).

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA No. 216818. Sun denies any remaining allegations set forth in paragraph 50.

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.

ANSWER: Sun admits that ANDA No. 216818 was filed containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents. Sun denies any remaining allegations set forth in paragraph 51.

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."

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents. Sun denies any remaining allegations set forth in paragraph 52.

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."

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents. Sun denies any remaining allegations set forth in paragraph 53.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed

containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents. Sun denies any remaining allegations set forth in paragraph 54.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents. Sun denies any remaining allegations set forth in paragraph 55.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents. Sun denies any remaining allegations set forth in paragraph 56.

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

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. Sun denies any remaining allegations set forth in paragraph 57.

COUNT I
(INFRINGEMENT OF THE '057 PATENT)

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

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-57 as if fully set forth herein.

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.

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA 216818 and that ANDA 216818 was filed with a Paragraph IV Certification to the '057 patent. Sun denies the remaining allegations set forth in paragraph 59.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '057 patent. Sun denies any remaining allegations set forth in paragraph 60.

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.

ANSWER: Denied.

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®.

ANSWER: Denied.

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

ANSWER: Paragraph 63 states a legal conclusion to which no answer is required. Sun denies the remaining allegations set forth in paragraph 63.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 72 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 72.

COUNT II
(INFRINGEMENT OF THE '803 PATENT)

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

ANSWER: Sun hereby incorporates by reference its responses to paragraph 1-72 as if fully set forth herein.

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.

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA 216818 and that ANDA 216818 was filed with a Paragraph IV Certification to the '803 patent. Sun denies the remaining allegations set forth in paragraph 74.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '803 patent. Sun denies any remaining allegations set forth in paragraph 75.

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.

ANSWER: Denied.

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®.

ANSWER: Denied.

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

ANSWER: Paragraph 78 states a legal conclusion to which no answer is required. Sun denies the remaining allegations set forth in paragraph 78.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 87 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 87.

COUNT III
(INFRINGEMENT OF THE '553 PATENT)

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

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-87 as if fully set forth herein.

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.

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA 216818 and that ANDA 216818 was filed with a Paragraph IV Certification to the '553 patent. Sun denies the remaining allegations set forth in paragraph 89.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '553 patent. Sun denies any remaining allegations set forth in paragraph 90.

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.

ANSWER: Denied.

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®.

ANSWER: Denied.

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

ANSWER: Paragraph 93 states a legal conclusion to which no answer is required. Sun denies the remaining allegations set forth in paragraph 93.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 102 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 102.

COUNT IV
(INFRINGEMENT OF THE '547 PATENT)

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

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-102 as if fully set forth herein.

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.

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA 216818 and that ANDA 216818 was filed with a Paragraph IV Certification to the '547 patent. Sun denies the remaining allegations set forth in paragraph 104.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '547 patent. Sun denies any remaining allegations set forth in paragraph 105.

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.

ANSWER: Denied.

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®.

ANSWER: Denied.

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

ANSWER: Paragraph 108 states a legal conclusion to which no answer is required. Sun denies the remaining allegations set forth in paragraph 108.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 117 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 117.

COUNT V
(INFRINGEMENT OF THE '087 PATENT)

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

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-117 as if fully set forth herein.

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.

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA 216818 and that ANDA 216818 was filed with a Paragraph IV Certification to the '087 patent. Sun denies the remaining allegations set forth in paragraph 119.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '087 patent. Sun denies any remaining allegations set forth in paragraph 120.

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.

ANSWER: Denied.

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®.

ANSWER: Denied.

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

ANSWER: Paragraph 123 states a legal conclusion to which no answer is required. Sun denies the remaining allegations set forth in paragraph 123.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 132 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 132.

COUNT VI
(INFRINGEMENT OF THE '347 PATENT)

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

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-132 as if fully set forth herein.

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.

ANSWER: Sun admits that SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA 216818 and that ANDA 216818 was filed with a Paragraph IV Certification to the '347 patent. Sun denies the remaining allegations set forth in paragraph 134.

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.

ANSWER: Sun admits that it complied with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95 by, *inter alia*, notifying Plaintiffs in writing that ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '347 patent. Sun denies any remaining allegations set forth in paragraph 135.

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®.

ANSWER: Denied.

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

ANSWER: Paragraph 137 states a legal conclusion to which no answer is required. Sun denies the remaining allegations set forth in paragraph 137.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 143 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 143.

REQUEST FOR RELIEF

Sun denies that Plaintiffs are entitled to any judgment or relief against Sun and, therefore, specifically denies paragraphs A through GG of Plaintiffs' Prayer for Relief.

GENERAL DENIAL

Sun denies all remaining allegations not specifically admitted herein. Sun further denies that Plaintiffs are entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the responses and denials set forth in Sun's Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Sun asserts the following separate defenses to the Complaint:

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of United States 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, the "Patents-in-Suit") are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

THIRD DEFENSE

Sun does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the Patents-in-Suit, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE

The Complaint fails to state a claim for an exceptional case and/or willful infringement under 25 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Sun's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

FIFTH DEFENSE

Plaintiffs may not seek injunctive relief against Sun because Plaintiffs' alleged damages are not immediate or irreparable.

ADDITIONAL DEFENSES

Sun reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

COUNTERCLAIMS

Counterclaim-Plaintiffs Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively "Sun"), by and through the undersigned attorneys, hereby asserts the following counterclaims against Plaintiffs/Counterclaim-Defendants Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively "Counterclaim-Defendants").

THE PARTIES

1. Counterclaim Plaintiff Sun Pharmaceutical Industries Ltd. ("SPIL") has a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063.

2. Counterclaim Plaintiff Sun Pharmaceutical Industries Inc. ("SPI") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2 Independence Way, Princeton, New Jersey, 08540.

3. SPIL is the owner of ANDA No. 216818 and seeks FDA approval of ANDA No. 216818.

4. According to Plaintiffs/Counterclaim-Defendants' allegations, Otsuka purports to be 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.

5. According to Plaintiffs/Counterclaim-Defendants' allegations, Lundbeck purports to be 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.

NATURE OF THE ACTION

6. Sun seeks a declaratory judgment that the claims of the '057, '803, '553, '547, '087, and '347 patents are invalid and/or will not be infringed by Sun.

JURISDICTION AND VENUE

7. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. The Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Without prejudice, venue is proper in this District for purposes of these counterclaims because Plaintiffs/Counterclaim-Defendants have commenced and continue to prosecute this action in this District.

10. Plaintiffs/Counterclaim-Defendants are subject to personal jurisdiction in this District because they commenced and continue to prosecute this action in this District.

BACKGROUND

11. Plaintiffs/Counterclaim-Defendants have alleged in the instant action that they are the owner of all legal rights, title, and interests in the '057, '803, '553, '547, '087, and '347 patents.

12. Upon information and belief, and according to Plaintiffs/Counterclaim-Defendants' allegations, Otsuka is the holder of NDA No. 202971 for ABILIFY MAINTENA®.

13. The '057, '803, '553, '547, '087, and '347 patents are listed in the electronic version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for ABILIFY MAINTENA® (aripiprazole for extended-release injectable suspension).

14. ANDA No. 216818 was filed with a Paragraph IV Certification to the '057, '803, '553, '547, '087, and '347 patents.

15. In compliance with 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95, Plaintiffs/Counterclaim-Defendants' were notified in writing that, *inter alia*, ANDA No. 216818 had been filed containing a Paragraph IV Certification with respect to the '057, '803, '553, '547, '087, and '347 patents.

COUNT 1
(Declaratory Judgment of Noninfringement of the '057, '803, '553, '547, '087, and '347 Patents)

16. Paragraphs 1-15 of the Counterclaims are incorporated as if fully set forth herein.

17. Plaintiffs/Counterclaim-Defendants have accused Sun of infringing claims of the '057, '803, '553, '547, '087, and '347 patents in connection with ANDA No. 216818.

18. Sun has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '057, '803, '553, '547, '087, and '347 patents.

19. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Sun believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Sun is infringing the claims of the '057, '803, '553, '547, '087, and '347 patents, and will continue to interfere with Sun's business.

20. Sun will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the '057, '803, '553, '547, '087, and '347 patents and from interfering with Sun's business.

21. A definite and concrete, real and substantial, justiciable controversy exists between Sun and Plaintiffs/Counterclaim-Defendants concerning Sun's noninfringement of the '057, '803, '553, '547, '087, and '347 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

22. Sun is entitled to declaratory judgment that Sun's proposed aripiprazole product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '057, '803, '553, '547, '087, and '347 patents.

COUNT 2
(Declaratory Judgment of Invalidity of the '057, '803, '553, '547, '087, and '347 Patents)

23. Paragraphs 1-22 of the Counterclaims are incorporated as if fully set forth herein.

24. The claims of the '057, '803, '553, '547, '087, and '347 patents are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

25. The alleged inventions of the '057, '803, '553, '547, '087, and '347 patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '057, '803, '553, '547, '087, and '347 patents is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '057, '803, '553, '547, '087, and '347 patents and would have had a reasonable expectation of success in doing so.

26. The claims of the '057, '803, '553, '547, '087, and '347 patents are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '057, '803, '553, '547, '087, and '347 patents and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

27. Unless Plaintiff/Counterclaim-Defendants are enjoined, Sun believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Sun infringes the claims of the '057, '803, '553, '547, '087, and '347 patents and will continue to interfere with Sun's business.

28. Sun will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the '057, '803, '553, '547, '087, and '347 patents and from interfering with Sun's business.

29. A definite and concrete, real and substantial, justiciable controversy exists between Sun and Plaintiffs/Counterclaim-Defendants concerning the invalidity of the '057, '803, '553, '547, '087, and '347 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

30. Sun is entitled to a declaratory judgment that the claims of the '057, '803, '553, '547, '087, and '347 patents are invalid.

COUNT 3
(Declaratory Judgment of No Injunctive Remedy for the '057, '803, '553, '547, '087, and '347 Patents)

31. Paragraphs 1-30 of the Counterclaims are incorporated as if fully set forth herein.

32. Plaintiffs/Counterclaim-Defendants cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

33. Plaintiffs/Counterclaim-Defendants are not entitled to any injunctive remedy of any kind.

34. A definite and concrete, real and substantial, justiciable controversy exists between Sun and Plaintiffs/Counterclaim-Defendants concerning the existence of no injunctive remedy for alleged infringement of the '057, '803, '553, '547, '087, and '347 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

35. Sun is entitled to a declaratory judgment that Plaintiffs/Counterclaim-Defendants are not entitled to any injunctive remedy of any kind regarding any alleged infringement of the claims of the '057, '803, '553, '547, '087, and '347 patents.

EXCEPTIONAL CASE

This case is an exceptional one, and Sun is entitled to an award of its reasonable attorneys' fees, costs, and expenses under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Sun respectfully requests that this Court enter judgment:

a. Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment be entered in favor of Sun;

b. Declaring that Plaintiffs/Counterclaim-Defendants are not entitled to any declaratory or injunctive relief or any alleged damages for alleged patent infringement by Sun;

c. Declaring that Sun does not infringe, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '057, '803, '553, '547, '087, and '347 patents;

d. Declaring that the '057, '803, '553, '547, '087, and '347 patents are invalid;

e. Enjoining Plaintiffs/Counterclaim-Defendants and their officers, employees, agents, representatives, attorneys, and others acting on their behalf from representing to anyone, either directly or indirectly, that Sun has infringed, is infringing, or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claim of the '057, '803, '553, '547, '087, and '347 patents;

f. Awarding Sun its costs;

g. Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Sun its attorneys' fees; and

h. Awarding to Sun such further relief as this Court may deem necessary, just and proper.

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Dated: May 7, 2025

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