UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, SUN PHARMA USA and CARACO PHARMACEUTICAL LABORATORIES, LTD., Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc. ("Sun Inc."), Sun Pharma Global FZE, Sun Pharma USA ("Sun USA") and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") (collectively, "Defendants"), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Sun Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri - Kurla Road, Andheri (E), Mumbai, 400 059, India.

3. Upon information and belief, Sun Inc. is a corporation organized and existing under the laws of the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Upon information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd.

4. Upon information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), Sharjah, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Inc.

5. Upon information and belief, Sun USA is a wholly-owned subsidiary and the United States arm of Sun Ltd., with its principal place of business at 1150 Elijah McCoy Drive, Detroit, MI, 48202.

6. Upon information and belief, Caraco is a corporation organized and existing under the laws of Michigan, having a facility at 270 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Caraco is a wholly-owned subsidiary of Sun USA. Upon information and belief, Caraco is an authorized agent of Sun Pharma Global FZE. Upon information and belief, Caraco may also be doing business as Sun Pharmaceutical Industries, Inc.

NATURE OF THE ACTION

7. This is an action for infringement of U.S. Patent No. 8,017,615 ("the '615 patent"), U.S. Patent No. 8,580,796 ("the '796 patent") and U.S. Patent No. 8,642,760 ("the '760 patent"), 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 Sun Pharma Global FZE's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food,

Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell and offer to sell generic pharmaceutical products ("Sun Pharma Global FZE's generic products") before the expiration of the asserted patents.

JURISDICTION AND VENUE

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

9. Upon information and belief, this Court has jurisdiction over Sun Ltd. Sun Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Ltd., directly or through its wholly-owned subsidiaries, including Sun Inc., Sun Pharma Global FZE, Sun USA and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Upon information and belief, this Court has jurisdiction over Sun Inc. 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 through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global FZE, Sun USA and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

11. Upon information and belief, this Court has jurisdiction over Sun Pharma Global FZE. Sun Pharma Global FZE is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global FZE, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Inc., Sun USA and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sun Pharma Global FZE purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Inc., Sun USA and Caraco, in this judicial district and this judicial district is a likely destination of Sun Pharma Global FZE's generic products. Sun Pharma Global FZE's authorized agent in this judicial district is John L. Dauer Jr., Esq., Chief Patent Counsel, Caraco Pharmaceutical Laboratories, Ltd., 270 Prospect Plains Rd., Cranbury, NJ 08512. Additionally, Sun Pharma Global FZE has availed itself of the laws of New Jersey by, at least, indicating that an offer to access confidential information relating to Sun Pharma Global FZE's ANDA No. 78-614 "shall be governed by the laws of the State of New Jersey." Upon information and belief, Sun Pharma Global FZE has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Upon information and belief, this Court has jurisdiction over Sun USA. Sun USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun USA, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Inc., Sun Pharma Global FZE and Caraco, manufactures, markets, imports and sells generic drugs

throughout the United States and in this judicial district. Upon information and belief, Caraco's website states:

> Sun Pharma USA is the US arm of Sun Pharmaceutical Industries, Ltd. ("Sun Pharma"), a leading pharmaceutical company in India. Sun Pharma USA consists of Sun Pharma subsidiaries Caraco Pharmaceutical Laboratories, Ltd. with locations in the Detroit, MI area, New Jersey and Ohio . . . .

See http://www.caraco.com/aspx/CorporateProfile.aspx (emphasis added) (accessed June 4, 2014).

13. Upon information and belief, this Court has jurisdiction over Caraco. Caraco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Caraco, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Inc., Sun Pharma Global FZE and Sun USA, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Caraco is Sun Pharma Global FZE's authorized agent in connection with ANDA No. 78-614. Upon information and belief, Caraco has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Upon information and belief, the Defendants hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

15. Upon information and belief, the Defendants work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

16. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

17. The U.S. Patent and Trademark Office ("PTO") issued the '615 patent on September 13, 2011, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '615 patent is attached as Exhibit A.

18. Otsuka is the owner of the '615 patent by virtue of assignment.

19. The '615 patent expires on December 16, 2024 (including pediatric exclusivity).

20. The '615 patent is directed to and claims, *inter alia,* pharmaceutical solid oral preparations and processes for preparing pharmaceutical solid oral preparations.

21. Otsuka is the holder of New Drug Application ("NDA") No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

22. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

23. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

24. Upon information and belief, Sun Pharma Global FZE submitted ANDA No. 78-614 to the FDA, under Section 505(j), seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products in the United States.

25. Otsuka received a letter from Sun Pharma Global FZE's authorized agent, Caraco, dated May 23, 2014, ("Sun Pharma Global FZE's Letter") purporting to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '615 patent.

26. Sun Pharma Global FZE's Letter states that "the established name of the proposed drug product that is the subject of the SUN ANDA is Aripiprazole Tablets."

27. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

28. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '615 patent.

29. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

SECOND COUNT FOR PATENT INFRINGEMENT

30. Otsuka realleges, and incorporates in full herein, paragraphs 21, 23, 24 and 26.

31. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

32. Otsuka is the owner of the '796 patent by virtue of assignment.

33. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

34. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

35. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

36. Sun Pharma Global FZE's Letter purports to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent.

37. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

38. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '796 patent.

39. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

THIRD COUNT FOR PATENT INFRINGEMENT

40. Otsuka realleges, and incorporates in full herein, paragraphs 21, 23, 24 and 26.

41. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

42. Otsuka is the owner of the '760 patent by virtue of assignment.

43. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

44. The '760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

45. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

46. Sun Pharma Global FZE's Letter purports to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent.

47. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

48. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '760 patent by submitting, or causing to be submitted

to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '760 patent.

49. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), the Defendants have infringed at least one claim of the '615 patent through Sun Pharma Global FZE's submission of ANDA No. 78-614 to the FDA to obtain approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products in the United States before the expiration of the '615 patent;

2) order that the effective date of any approval by the FDA of Sun Pharma Global FZE's generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;

3) enjoin the Defendants from the manufacture, use, sale, offer to sell and import of Sun Pharma Global FZE's generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin the Defendants and all persons acting in concert with the Defendants from seeking, obtaining or maintaining approval of ANDA No. 78-614 until the expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), the Defendants have infringed at least one claim of the '796 patent through Sun Pharma Global FZE's submission of ANDA No. 78-614 to the FDA to obtain approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products in the United States before the expiration of the '796 patent;

6) order that the effective date of any approval by the FDA of Sun Pharma Global FZE's generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;

7) enjoin the Defendants from the manufacture, use, sale, offer to sell and import of Sun Pharma Global FZE's generic products until the expiration of the '796 patent, or such later date as the Court may determine;

8) enjoin the Defendants and all persons acting in concert with the Defendants, from seeking, obtaining or maintaining approval of ANDA No. 78-614 until the expiration of the '796 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), the Defendants have infringed at least one claim of the '760 patent through Sun Pharma Global FZE's submission of ANDA No. 78-614 to the FDA to obtain approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products in the United States before the expiration of the '760 patent;

10) order that the effective date of any approval by the FDA of Sun Pharma Global FZE's generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;

11) enjoin the Defendants from the manufacture, use, sale, offer to sell and import of Sun Pharma Global FZE's generic products until the expiration of the '760 patent, or such later date as the Court may determine;

12) enjoin the Defendants and all persons acting in concert with the Defendants, from seeking, obtaining or maintaining approval of ANDA No. 78-614 until the expiration of the '760 patent;

13) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and

14) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

s/John F. Brenner
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