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Otsuka Pharmaceutical Co., Ltd.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____)	
OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
SANDOZ INC., SANDOZ PRIVATE LTD.)	
and SANDOZ INTERNATIONAL GMBH,)	
)	
Defendants.)	
_____)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Sandoz Inc., Sandoz Private Ltd. and Sandoz International GmbH (collectively “Sandoz”), 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, Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540. Upon information and belief, Sandoz Inc. is a subsidiary of Sandoz International GmbH.

3. Upon information and belief, Sandoz Private Ltd. is a private limited liability company organized and existing under the laws of India, having its principal place of business at MIDC, Plot No. 8 A/2, 8B, T.T.C. Industrial Area, Kalwe Block, Village-Digha, Opp. Thane-Belapur Road, Navi Mumbai 400 708, India.

4. Upon information and belief, Sandoz International GmbH is a private limited liability company organized and existing under the laws of Germany, having its principal place of business at Industriestrasse 25, Holzkirchen 83607, Germany.

NATURE OF THE ACTION

5. 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”), U.S. Patent No. 8,642,760 (“the ’760 patent”) and U.S. Patent No. 8,759,350 (“the ’350 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 Sandoz Inc.’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, import, sell and offer to sell generic pharmaceutical products (“Sandoz’s generic products”) prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

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

7. This Court has jurisdiction over Sandoz Inc. Upon information and belief, Sandoz Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sandoz Inc., directly or indirectly, manufactures, imports, markets and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Sandoz Inc. purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Sandoz's generic products. Upon information and belief, Sandoz Inc. is registered as a Manufacturer and Wholesaler in the State of New Jersey (No. 5003732). *See* New Jersey Drug Registration and Verification, at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx>. Upon information and belief, Sandoz Inc. is registered to do business in New Jersey under Business I.D. No. 0100097265. *See* <http://www.njportal.com/DOR/BusinessNameSearch>. Sandoz 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.

8. This Court has jurisdiction over Sandoz Private Ltd. Upon information and belief, Sandoz Private Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sandoz Private Ltd., directly or indirectly, including through Sandoz Inc. located in New Jersey, manufactures, markets, imports, and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Sandoz Private Ltd. is a Drug Master File (DMF) holder for aripiprazole.

9. This Court has jurisdiction over Sandoz International GmbH. Upon information and belief, Sandoz International GmbH is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sandoz International GmbH, directly or indirectly, including through Sandoz Inc. located in New Jersey, manufactures, imports, markets and sells generic drug products throughout the United States and in this judicial district.

10. Upon information and belief, Sandoz Inc., Sandoz Private Ltd. and Sandoz International GmbH operate as a single integrated business and hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic drug products throughout the United States, including in this judicial district. *See, e.g.*, www.novartis.com and www.sandoz.com.

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

FIRST COUNT FOR PATENT INFRINGEMENT

12. 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.

13. Otsuka is the owner of the ’615 patent by virtue of assignment.

14. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

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

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

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

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

19. Upon information and belief, Sandoz Inc. submitted ANDA No. 78-611 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Sandoz’s generic products in the United States.

20. Otsuka received a letter from Sandoz Inc. dated January 29, 2015, purporting to include a Notice of Certification for ANDA No. 78-611 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (“Sandoz Inc.’s 78-611 letter”) as to the '615 patent.

21. Sandoz Inc.’s 78-611 letter alleges that the established name of the drug products that are the subject of Sandoz Inc.’s ANDA is “Aripiprazole Tablet, 2mg, 5mg, 10mg, 15mg, 20mg and 30mg.”

22. Upon information and belief, Sandoz’s generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-611 seeking approval to manufacture, use, import, offer to sell and sell Sandoz’s generic products before the expiration date of the '615 patent.

24. Upon information and belief, Sandoz Inc.’s actions relating to Sandoz Inc.’s ANDA No. 78-611 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Sandoz Inc., Sandoz Private Ltd. and Sandoz International GmbH.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 1-24.
26. 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.
27. Otsuka is the owner of the '796 patent by virtue of assignment.
28. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).
29. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.
30. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.
31. Sandoz Inc.'s 78-611 letter purports to include a Notice of Certification for ANDA No. 78-611 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '796 patent.
32. Upon information and belief, Sandoz's generic products will, if approved and marketed, infringe at least one claim of the '796 patent.
33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-611 seeking approval to manufacture, use, import, offer to sell and sell Sandoz's generic products before the expiration date of the '796 patent.
34. Upon information and belief, Sandoz Inc.'s actions relating to Sandoz Inc.'s ANDA No. 78-611 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Sandoz Inc., Sandoz Private Ltd. and Sandoz International GmbH.

THIRD COUNT FOR PATENT INFRINGEMENT

35. Otsuka realleges, and incorporates in full herein, paragraphs 1-34.

36. 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.

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

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

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

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

41. Sandoz Inc.'s 78-611 letter purports to include a Notice of Certification for ANDA No. 78-611 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '760 patent.

42. Upon information and belief, Sandoz's generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-611 seeking approval to manufacture, use, import, offer to sell and sell Sandoz's generic products before the expiration date of the '760 patent.

44. Upon information and belief, Sandoz Inc.'s actions relating to Sandoz Inc.'s ANDA No. 78-611 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Sandoz Inc., Sandoz Private Ltd. and Sandoz International GmbH.

FOURTH COUNT FOR PATENT INFRINGEMENT

45. Otsuka realleges, and incorporates in full herein, paragraphs 1-44.

46. The U.S. Patent and Trademark Office (“PTO”) issued the ’350 patent on June 24, 2014, entitled “Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders.” A copy of the ’350 patent is attached as Exhibit D.

47. Otsuka is the owner of the ’350 patent by virtue of assignment.

48. The ’350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

49. The ’350 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment.

50. Otsuka lists the ’350 patent in the Orange Book for NDA No. 21-436.

51. Sandoz Inc.’s 78-611 letter purports to include a Notice of Certification for ANDA No. 78-611 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’350 patent.

52. Upon information and belief, Sandoz’s generic products will, if approved and marketed, infringe at least one claim of the ’350 patent.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the ’350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-611 seeking approval to manufacture, use, import, offer to sell and sell Sandoz’s generic products before the expiration of the ’350 patent.

54. Upon information and belief, Sandoz Inc.’s actions relating to Sandoz Inc.’s ANDA No. 78-611 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Sandoz Inc., Sandoz Private Ltd. and Sandoz International GmbH.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Sandoz 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), Sandoz has infringed at least one claim of the '615 patent through Sandoz Inc.'s submission of ANDA No. 78-611 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Sandoz'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 Sandoz'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 Sandoz from the manufacture, use, import, offer for sale and sale of Sandoz's generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Sandoz and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz Inc.'s ANDA No. 78-611 until expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '796 patent through Sandoz Inc.'s submission of ANDA No. 78-611 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Sandoz'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 Sandoz'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 Sandoz from the manufacture, use, import, offer for sale and sale of Sandoz's generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 8) enjoin Sandoz and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz Inc.'s ANDA No. 78-611 until expiration of the '796 patent;
- 9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '760 patent through Sandoz Inc.'s submission of ANDA No. 78-611 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Sandoz'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 Sandoz'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 Sandoz from the manufacture, use, import, offer for sale and sale of Sandoz's generic products until the expiration of the '760 patent, or such later date as the Court may determine;
- 12) enjoin Sandoz and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz Inc.'s ANDA No. 78-611 until expiration of the '760 patent;

- 13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed at least one claim of the '350 patent through Sandoz Inc.'s submission of ANDA No. 78-611 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Sandoz's generic products in the United States before the expiration of the '350 patent;
- 14) order that the effective date of any approval by the FDA of Sandoz's generic products be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;
- 15) enjoin Sandoz from the manufacture, use, import, offer for sale and sale of Sandoz's generic products until the expiration of the '350 patent, or such later date as the Court may determine;
- 16) enjoin Sandoz and all persons acting in concert with Sandoz, from seeking, obtaining or maintaining approval of Sandoz Inc.'s ANDA No. 78-611 until expiration of the '350 patent;
- 17) 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
- 18) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

s/Melissa A. Chuderewicz
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