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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD. Plaintiff, v. APOTEX CORP. and APOTEX INC. Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex"), 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, Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Weston, Toronto, Ontario, Canada M9L IT9.

NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Numbers 6,977,257 ("the '257 patent") and 5,006,528 ("the '528 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 Apotex 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 market a generic pharmaceutical product ("Apotex's generic product").

JURISDICTION AND VENUE

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

6. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. directly, or indirectly, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Apotex Corp.'s generic products. Upon information and belief, Apotex Corp. has previously submitted to the

jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court has jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Inc. directly, or through its wholly-owned subsidiaries (primarily Apotex Corp.), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

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

FIRST COUNT FOR PATENT INFRINGEMENT

9. The U.S. Patent and Trademark Office ("PTO") issued the '257 patent on December 20, 2005, entitled "Aripiprazole Oral Solution." A copy of the '257 patent is attached as Exhibit A.

10. The '257 patent is assigned to Otsuka. Otsuka is the owner of the '257 patent as recorded by the PTO at Reel 017586, Frame 0036.

11. The '257 patent expires on October 24, 2022 (including pediatric exclusivity).

12. The '257 patent claims, *inter alia,* oral aripiprazole solutions.

13. Otsuka is the holder of NDA No. 21-713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. The Orange Book lists the '257 patent for NDA No. 21-713.

14. Otsuka manufactures and sells aripiprazole oral solution in the United States under the trademark Abilify®.

15. Upon information and belief, Apotex filed with the FDA ANDA No. 20-4094, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

16. Upon information and belief, Apotex's ANDA No. 20-4094 seeks FDA approval to sell in the United States Apotex's generic product.

17. Otsuka received a letter from Apotex dated July 27, 2012, purporting to include a Notice of Certification for ANDA No. 20-4094 ("Apotex's 20-4094 letter") under 21 U.S.C. § 355(j)(1), § 355(j)(2)(A), § 355(j)(2)(B)(iv)(I), and § 355(j)(2)(B)(iv)(II); and 21 C.F.R. § 314.95(c)(1) and § 314.95(c)(6).

18. Apotex's 20-4094 letter alleges that the active ingredient in Apotex's generic product for which it seeks approval is aripiprazole.

19. Upon information and belief, Apotex's generic product will, if approved and marketed, infringe at least one claim of the '257 patent.

20. Under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '257 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4094 seeking approval for the commercial marketing of Apotex's generic product before the expiration date of the '257 patent.

21. Upon information and belief, Apotex's actions relating to Apotex's ANDA No. 20-4094 complained of herein were done with the cooperation, participation, and assistance, and for the benefit, of Apotex Inc. and Apotex Corp.

SECOND COUNT FOR PATENT INFRINGEMENT

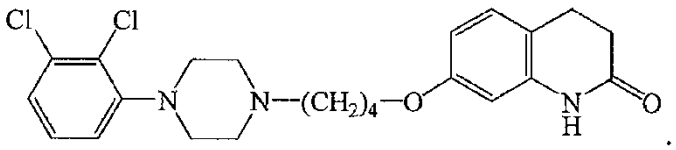
22. The PTO issued the '528 patent on April 9, 1991, entitled "Carbostyril Derivatives." A copy of the '528 patent is attached as Exhibit B.

23. The '528 patent is assigned to Otsuka. Otsuka is the owner of the '528 patent as recorded by the PTO at Reel 014402, Frame 0284.

24. The PTO issued a Patent Term Extension under 35 U.S.C. § 156 on October 12, 2005. The '528 patent expires on April 20, 2015 (with pediatric exclusivity). A copy of the Patent Term Extension for the '528 patent is attached as Exhibit C.

25. The PTO issued a Reexamination Certificate for the '528 patent on June 13, 2006. A copy of the Reexamination Certificate for the '528 patent is attached as Exhibit D.

26. The '528 patent claims, *inter alia*, aripiprazole. The chemical structure for aripiprazole is:



27. Otsuka is the holder of New Drug Application ("NDA") No. 21-713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. The Orange Book lists the '528 patent for NDA No. 21-713.

28. Otsuka manufactures and sells aripiprazole oral solution in the United States under the trademark Abilify®.

29. Upon information and belief, Apotex Inc. filed with the FDA ANDA No. 20-4094, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

30. Upon information and belief, Apotex's ANDA No. 20-4094 seeks FDA approval to sell in the United States Apotex's generic product.

31. Otsuka received a letter from Apotex dated July 27, 2012, purporting to include a Notice of Certification for ANDA No. 20-4094 ("Apotex's 20-4094 letter") under 21 U.S.C. § 355(j)(1), § 355(j)(2)(A), § 355(j)(2)(B)(iv)(I), and § 355(j)(2)(B)(iv)(II); and 21 C.F.R. § 314.95(c)(1) and § 314.95(c)(6).

32. Apotex's 20-4094 letter alleges that the active ingredient in Apotex's generic product for which it seeks approval is aripiprazole.

33. Upon information and belief, Apotex's generic product will, if approved and marketed, infringe claims 12, 17 and 23 of the '528 patent.

34. Under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed claims 12, 17 and 23 of the '528 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4094 seeking approval for the commercial marketing of Apotex's generic product before the expiration date of the '528 patent.

35. In a related action, this Court has confirmed the validity and enforceability of claims 12, 17 and 23 of the '528 patent. *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc. et al*., 3:07-cv-01000, D.I. 392-393, Amended Order and Final Judgment (D.N.J. December 15, 2010). Apotex joined an appeal to the Federal Circuit challenging this Court's decision with respect to the validity of the asserted claims of the '528 patent. The Federal Circuit, however, confirmed the validity of the asserted claims of the '528 patent on May 7, 2012, and issued its mandate on August 14, 2012 in the appeal captioned *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc., et al.* (Appeal Nos. 2011-1126, -1127). Nevertheless, Apotex's 20-4094 letter contests the validity of these same claims.

36. Upon information and belief, Apotex's actions relating to Apotex's ANDA No. 20-4094 complained of herein were done with the cooperation, the participation, the assistance, and for the benefit, of Apotex Inc. and Apotex Corp.

37. **WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Apotex Corp. and Apotex Inc. 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), Apotex has infringed at least one claim of the '257 patent through Apotex's submission of ANDA No. 20-4094 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic product before the expiration of the '257 patent;

2) order that the effective date of any approval by the FDA of Apotex's generic product be a date that is not earlier than the expiration of the '257 patent, or such later date as the Court may determine;

3) enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or sale of Apotex's generic products until the expiration of the '257 patent, or such later date as the Court may determine;

4) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 20-4094 until the expiration of the '257 patent;

5) enter judgment that, under 35 U.S.C. § 271 (e)(2)(A), Apotex has infringed claims 12, 17 and 23 of the '528 patent through Apotex's submission of ANDA No. 20-4094 to the FDA to obtain approval for the commercial manufacture, use, import,

offer for sale and/or sale in the United States of Apotex's generic product before the expiration of the '528 patent;

6) order that the effective date of any approval by the FDA of Apotex's generic product be a date that is not earlier than the expiration of the '528 patent, or such later date as the Court may determine;

7) enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or sale of Apotex's generic product until the expiration of the '528 patent, or such later date as the Court may determine;

8) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 20-4094 until the expiration of the '528 patent;

9) 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

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

Respectfully submitted,

/s/ John F. Brenner

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