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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (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, Teva USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1090 Horsham Rd., North Wales, PA 19454.

3. Upon information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Bazel, Petah Tikva, Israel, 004951033. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

NATURE OF THE ACTION

4. This is an action for infringement of 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 Teva USA'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 ("Teva USA's generic products") before the expiration of the asserted patents.

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 Teva USA. Teva USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva USA, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States

and in this judicial district. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is the likely destination of Teva USA's generic products. Upon information and belief, Teva USA operates and maintains branches in Waldwick, New Jersey; Englewood Cliffs, New Jersey; Fairfield, New Jersey and Fair Lawn, New Jersey. Upon information and belief, Teva USA is registered in the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler" of drugs, with Registration Nos. 5003436 and 5000583. Teva USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court has jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd., directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. According to its website, "Teva is the leading generics company in America, with $20.3 billion in net revenues in 2012. . . . Over 1.5 million Teva prescriptions are written each day in the US alone, or 1,073 prescriptions per minute, while 1 out of every 6 generic prescriptions in the US and Canada is filled with a Teva product." *See* http://www.tevapharm.com/Pages/Teva-Worldwide.aspx. Upon information and belief, Teva Ltd. sells aripiprazole through its subsidiary, Teva API, Inc., which is located at 500 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. *See* http://www.tapi.com /Public/Documents/tapi%20product%20catalogue.pdf. Teva Ltd. has previously submitted to the

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

8. Upon information and belief, the Defendants hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products. Upon information and belief, Teva Ltd.'s website states that Teva USA "is the U.S.-based generic arm" of Teva Ltd. *See* http://www.tevapharm.com/Media/News/Pages/2011/1590368.aspx?category=Generics.

9. 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.

10. 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

11. The U.S. Patent and Trademark Office ("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 A.

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

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

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

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

16. Otsuka lists the '796 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

18. Upon information and belief, Teva USA submitted ANDA No. 078608 to the FDA, under Section 505(j), seeking approval to manufacture, use, sell and offer to sell Teva USA's generic products in the United States.

19. Otsuka received a letter from Teva USA, dated August 7, 2014, ("Teva USA's Letter") purporting to include a Notice of Certification for ANDA No. 078608 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent.

20. Teva USA's Letter states that "the established name of the proposed drug product is Aripiprazole Tablets, 10 mg."

21. Upon information and belief, Teva USA's generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

22. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva USA has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 078608 seeking approval to manufacture, use, sell and offer to sell Teva USA's generic products before the expiration date of the '796 patent.

23. Upon information and belief, Teva USA's actions relating to ANDA No. 078608 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Teva USA and Teva Ltd.

SECOND COUNT FOR PATENT INFRINGEMENT

24. Otsuka realleges, and incorporates in full herein, paragraphs 15-20.

25. 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 B.

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

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

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

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

30. Teva USA's Letter purports to include a Notice of Certification for ANDA No. 078608 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent.

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

32. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva USA has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 078608 seeking approval to manufacture, use, sell and offer to sell Teva USA's generic products before the expiration date of the '760 patent.

33. Upon information and belief, Teva USA's actions relating to ANDA No. 078608 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Teva USA and Teva Ltd.

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 '796 patent through Teva USA's submission of ANDA No.

078608 to the FDA to obtain approval to manufacture, use, sell and offer to sell Teva USA's generic products in the United States before the expiration of the '796 patent;

2) order that the effective date of any approval by the FDA of Teva USA'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;

3) enjoin the Defendants from the manufacture, use, sale, offer for sale and import of Teva USA's generic products until the expiration of the '796 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. 078608 until the expiration of the '796 patent;

5) 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 Teva USA's submission of ANDA No. 078608 to the FDA to obtain approval to manufacture, use, sell and offer to sell Teva USA's generic products in the United States before the expiration of the '760 patent;

6) order that the effective date of any approval by the FDA of Teva USA'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;

7) enjoin the Defendants from the manufacture, use, sale, offer for sale and import of Teva USA's generic products until the expiration of the '760 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. 078608 until the expiration of the '760 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,

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Dated: September 19, 2014

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