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OTSUKA PHARMACEUTICAL CO., LTD.

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 Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), 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 under the laws of the State of Delaware, its principal place of business is located at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090, and its registered agent is Corporation Trust Company located at 820 Bear Tavern Road, West Trenton, New Jersey 08628.

3. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. Upon information and belief, Teva Ltd. is a corporation organized under the laws of Israel, and its principal place of business is located at 5 Basel Street, Petach Tikva 49131, Israel.

NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Numbers 5,006,528 ("the '528 patent") and 6,977,257 ("the '257 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 market a generic pharmaceutical product ("Teva'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 Teva USA. Upon information and belief, Teva USA is registered to do business in New Jersey, has branches in New Jersey, conducts business within this judicial district, and retains a registered agent in this judicial district. Upon information and belief, Teva USA directly, or indirectly, manufactures, markets 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 in this judicial district, and this judicial district is a likely destination of Teva's generic product.

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 through its wholly-owned subsidiaries (primarily Teva USA), conducts business within this judicial district. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

8. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. § § 1391(c) and (d), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

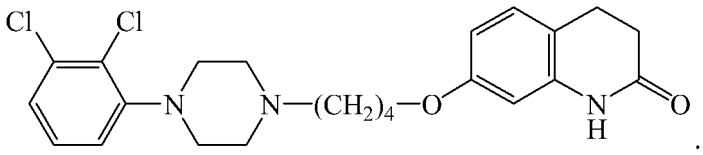
9. The U.S. Patent and Trademark Office ("PTO") issued the '528 patent on April 9, 1991, entitled "Carbostyril Derivatives." A copy of the '528 patent is attached as Exhibit A.

10. 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.

11. 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. A copy of the Patent Term Extension for the '528 patent is attached as Exhibit B.

12. 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 C.

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



14. Otsuka is the holder of New Drug Application ("NDA") No. 02-1436 for aripiprazole, which the FDA approved on November 15, 2002. Otsuka lists the '528 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 02-1436.

15. Otsuka is also the holder of NDA No. 02-1713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. Otsuka lists the '528 patent in the Orange Book for NDA No. 02-1713.

16. Otsuka manufactures and sells various dosage strengths of aripiprazole in the United States under the trademark Abilify®.

17. Upon information and belief, Teva USA filed with the FDA ANDA No. 90-251, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

18. Upon information and belief, Teva USA's ANDA No. 90-251 seeks FDA approval to sell in the United States a generic oral solution containing 1 mg/mL of aripiprazole ("Teva USA's generic aripiprazole oral solution").

19. On September 16, 2009, Otsuka received a letter from Teva USA dated September 15, 2009, purporting to be a Notice of Certification for ANDA No. 90-251 ("Teva USA's 09/15/09 letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c).

20. Teva USA's 09/15/09 letter alleges that the active ingredient in Teva USA's generic aripiprazole oral solution for which it seeks approval is aripiprazole.

21. Upon information and belief, Teva USA's generic aripiprazole oral solution will, if approved and marketed, infringe at least one claim of the '528 patent.

22. Under 35 U.S.C. § 271(e)(2)(A), Teva USA has infringed at least one claim of the '528 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-251 seeking approval for the commercial marketing of Teva USA's generic aripiprazole oral solution before the expiration date of the '528 patent.

23. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-251 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd.

SECOND COUNT FOR PATENT INFRINGEMENT

24. The PTO issued the '257 patent on December 20, 2005, entitled "Aripiprazole Oral Solution." A copy of the '257 patent is attached as Exhibit D.

25. 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.

26. The '257 patent expires on October 24, 2022.

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

28. Otsuka is the holder of NDA No. 02-1713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. Otsuka lists the '257 patent in the Orange Book for NDA No. 02-1713.

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

30. Upon information and belief, Teva USA filed with the FDA ANDA No. 90-251, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

31. Upon information and belief, Teva USA's ANDA No. 90-251 seeks FDA approval to sell in the United States Teva USA's generic aripiprazole oral solution.

32. On September 16, 2009, Otsuka received Teva USA's 09/15/09 letter under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c).

33. Teva USA's 09/15/09 letter alleges that the active ingredient in Teva USA's generic aripiprazole oral solution for which it seeks approval is aripiprazole.

34. Upon information and belief, Teva USA's generic aripiprazole oral solution will, if approved and marketed, infringe at least one claim of the '257 patent.

35. Under 35 U.S.C. § 271(e)(2)(A), Teva USA has infringed at least one claim of the '257 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-251 seeking approval for the commercial marketing of Teva USA's generic aripiprazole oral solution before the expiration date of the '257 patent.

36. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-251 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Teva USA and Teva Ltd. (collectively "Teva") 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), Teva has infringed at least one claim of the '528 patent through Teva USA's submission of ANDA No. 90-251 to the FDA to obtain approval for the commercial manufacture, use, import,

offer for sale and/or sale in the United States of Teva USA's generic aripiprazole oral solution before expiration of the '528 patent;

2) order that the effective date of any approval by the FDA of Teva USA's generic aripiprazole oral solution be a date that is not earlier than the expiration of the '528 patent, or such later date as the Court may determine;

3) enjoin Teva from the commercial manufacture, use, import, offer for sale and/or sale of Teva USA's generic aripiprazole oral solution until the expiration of the '528 patent, or such later date as the Court may determine;

4) enjoin Teva and all persons acting in concert with Teva, from seeking, obtaining or maintaining approval of Teva 's ANDA No. 90-251 until expiration of the '528 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '257 patent through Teva USA's submission of ANDA No. 90-251 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Teva USA's generic aripiprazole oral solution before expiration of the '257 patent;

6) order that the effective date of any approval by the FDA of Teva USA's generic aripiprazole oral solution be a date that is not earlier than the expiration of the '257 patent, or such later date as the Court may determine;

7) enjoin Teva from the commercial manufacture, use, import, offer for sale and/or sale of Teva USA's generic aripiprazole oral solution until the expiration of the '257 patent, or such later date as the Court may determine;

8) enjoin Teva and all persons acting in concert with Teva, from seeking, obtaining or maintaining approval of Teva USA's ANDA No. 90-251 until expiration of the '257 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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Dated: October 29, 2009