UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ZYDUS PHARMACEUTICALS USA INC. and CADILA HEALTHCARE LIMITED, Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Zydus Pharmaceuticals USA Inc. ("Zydus USA") and Cadila Healthcare Limited (collectively, "Zydus"), 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, Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

3. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Cadila Healthcare Limited (d/b/a "Zydus Cadila"). Upon information and belief, Cadila Healthcare

Limited is a corporation organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, Gujarat, India.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent No. 9,359,302 ("the '302 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 Zydus USA's filing of two Abbreviated New Drug Applications ("ANDAs") 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, offer to sell and sell generic pharmaceutical products ("Zydus USA's generic products") before the expiration of the asserted patent.

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 Zydus USA. Upon information and belief, Zydus USA was incorporated in New Jersey and has its principal place of business in New Jersey. Upon information and belief, Zydus USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Zydus USA, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Zydus USA purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Zydus USA's generic products. Upon information and belief, Zydus USA has previously submitted to the jurisdiction of this Court and has further previously

availed itself of this Court by asserting counterclaims in other civil action initiated in this jurisdiction.

7. Upon information and belief, this Court additionally has jurisdiction over Zydus USA because it has availed itself of the rights and benefits of this judicial district, having stated in its Offer of Confidential Access, executed May 7, 2014, that "[t]his Agreement shall be governed in accordance with the laws of the state of New Jersey without regard to its conflict-of-law rules."

8. Upon information and belief, this Court has jurisdiction over Cadila Healthcare Limited. Upon information and belief, Cadila Healthcare Limited is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Cadila Healthcare Limited, directly or through its subsidiary Zydus USA, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district.

9. Upon information and belief, Zydus USA and Cadila Healthcare Limited 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. 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 '302 patent on June 7, 2016, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '302 patent is attached as Exhibit A.

12. Otsuka is the owner of the '302 patent by virtue of assignment.

13. The '302 patent expires on September 25, 2022, excluding any pediatric exclusivity.

14. The '302 patent is directed to and claims, *inter alia,* aripiprazole crystals, pharmaceutical compositions and methods of treatment.

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 '302 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, Zydus USA submitted ANDA No. 90-472 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 generic products containing 2, 5, 10, 15, 20 and 30 mg of aripiprazole ("Zydus USA's tablet generic products") in the United States.

19. Otsuka received a letter from Zydus USA dated September 7, 2016, purporting to include a Notice of Certification for ANDA No. 90-472 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '302 patent. Otsuka also received a letter from Zydus USA dated September 8, 2016, purporting to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '302 patent. Both letters are referred to collectively herein as "Zydus USA's letter."

20. Zydus USA's letter alleges that Zydus USA's tablet generic products are "Aripiprazole Oral Tablets."

21. Upon information and belief, the manufacture, use, import, offer for sale and sale of Zydus USA's tablet generic products will, if approved and marketed, directly infringe at least one claim of the '302 patent.

22. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '302 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-472 seeking approval to manufacture, use, import, offer to sell and sell Zydus USA's tablet generic products before the expiration date of the '302 patent.

23. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-472 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

SECOND COUNT FOR PATENT INFRINGEMENT

24. Otsuka realleges, and incorporates in full herein, paragraphs 11-14 and 19.

25. Otsuka is the holder of NDA No. 21-729 for orally disintegrating tablets ("ODT") containing aripiprazole, which the FDA approved on June 7, 2006.

26. Otsuka lists the '302 patent in the Orange Book for NDA No. 21-729.

27. Upon information and belief, Zydus USA submitted ANDA No. 90-165 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 generic products containing 10, 15, 20 and 30 mg of aripiprazole ("Zydus USA's ODT generic products") in the United States.

28. Zydus USA's letter purports to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '302 patent.

29. Zydus USA's letter alleges that Zydus USA's ODT generic products are "Aripiprazole Orally Disintegrating Tablets."

30. Upon information and belief, the manufacture, use, import, offer for sale and sale of Zydus USA's ODT generic products will, if approved and marketed, directly infringe at least one claim of the '302 patent.

31. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '302 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-165 seeking approval to manufacture, use, import, offer to sell and sell Zydus USA's ODT generic products before the expiration date of the '302 patent.

32. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-165 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Zydus USA and Cadila Healthcare Limited 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), Zydus has infringed at least one claim of the '302 patent through Zydus USA's submission of ANDA No. 90-472 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Zydus USA's tablet generic products in the United States before the expiration of the '302 patent;

2) order that the effective date of any approval by the FDA of Zydus USA's tablet generic products be a date that is not earlier than the expiration of the '302 patent, or such later date as the Court may determine;

3) enjoin Zydus from the manufacture, use, import, offer for sale and sale of Zydus USA's tablet generic products until the expiration of the '302 patent, or such later date as the Court may determine;

4) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-472 until the expiration of the '302 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '302 patent through Zydus USA's submission of ANDA No. 90-165 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Zydus USA's ODT generic products in the United States before the expiration of the '302 patent;

6) order that the effective date of any approval by the FDA of Zydus USA's ODT generic products be a date that is not earlier than the expiration of the '302 patent, or such later date as the Court may determine;

7) enjoin Zydus from the manufacture, use, import, offer for sale and sale of Zydus USA's ODT generic products until the expiration of the '302 patent, or such later date as the Court may determine;

8) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-165 until the expiration of the '302 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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