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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.:
ZYDUS PHARMACEUTICALS USA, INC.)	
)	
and)	
)	
CADILA HEALTHCARE LTD.)	
)	
Defendants.)	
_____)	

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 Ltd. (“Cadila Healthcare”), 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 under the laws of the State of New Jersey, and its principal place of business is located at 210 Carnegie Center, Suite # 103, Princeton, New Jersey 08540.

3. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Cadila Healthcare (d/b/a "Zydus Cadila"). Upon information and belief, Cadila Healthcare is a corporation organized under the laws of India, and its principal place of business is located at Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, Gujarat, India.

NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Number 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 Zydus 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 generic pharmaceutical products ("Zydus's generic products").

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 is registered to do business in New Jersey, has an office in New Jersey, conducts business within this judicial district, and retains a registered agent in this judicial district. Upon information and belief, Zydus USA directly, or indirectly, manufactures,

markets 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 in this judicial district, and this judicial district is a likely destination of Zydus's generic products.

7. Upon information and belief, this Court has jurisdiction over Cadila Healthcare. Upon information and belief, Cadila Healthcare is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Cadila Healthcare directly, or through its wholly-owned subsidiaries (primarily Zydus USA), conducts business within this judicial district. Upon information and belief, Cadila Healthcare directly, or through its wholly-owned subsidiaries (primarily Zydus 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

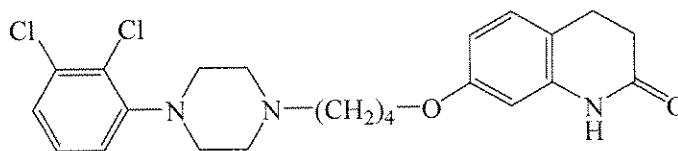
9. The U.S. Patent and Trademark Office ("PTO") issued the '528 patent on April 9, 1991, entitled "Carbostyryl Derivatives." A copy of the '528 patent is attached as Exhibit A.

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 October 20, 2014. 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. 02-1729 for orally disintegrating tablets (“ODT”) containing aripiprazole, which the FDA approved on June 7, 2006. Otsuka lists the '528 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 02-1729.

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

16. Upon information and belief, Zydus USA filed with the FDA ANDA No. 90-165, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

17. Upon information and belief, Zydus USA’s ANDA No. 90-165 seeks FDA approval to sell in the United States generic products containing 10, 15, 20 and 30 mg of aripiprazole (“Zydus USA’s ODT generic products”).

18. Otsuka received a letter from Zydus USA dated April 16, 2008, purporting to be a Notice of Certification for ANDA No. 90-165 (“Zydus USA’s 90-165 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).

19. Zydus USA’s 90-165 letter alleges that the active ingredient in Zydus USA’s ODT generic products for which it seeks approval is aripiprazole.

20. Upon information and belief, Zydus USA’s ODT generic products will, if approved and marketed, infringe at least one claim of the ‘528 patent.

21. Under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the ‘528 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-165 seeking approval for the commercial marketing of Zydus USA’s ODT generic products before the expiration date of the ‘528 patent.

22. Upon information and belief, Zydus USA’s actions relating to Zydus USA’s ANDA No. 90-165 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, Cadila Healthcare.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Zydus USA and Cadila Healthcare (collectively “Zydus”) 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 ‘528 patent through Zydus USA’s submission of ANDA No. 90-165 to the FDA to obtain approval for the commercial manufacture, use, import,

offer for sale and/or sale in the United States of Zydus USA's ODT generic products before expiration of the '528 patent;

- 2) 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 '528 patent, or such later date as the Court may determine;
- 3) enjoin Zydus from the commercial manufacture, use, import, offer for sale and/or sale of Zydus USA's ODT generic products until the expiration of the '528 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. 90-165 until expiration of the '528 patent;
- 5) 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
- 6) award Otsuka such further and additional relief as this Court deems just and proper.

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