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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

)	
OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
WOCKHARDT BIO AG, WOCKHARDT)	
USA LLC and WOCKHARDT LIMITED,)	
)	
)	
Defendants.)	
)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited (collectively, “Wockhardt”), 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, Wockhardt Bio AG is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Grafenauweg 6, 6300 Zug, Switzerland. Upon information and belief, Wockhardt Bio AG is a wholly-owned subsidiary of Wockhardt Limited.

3. Upon information and belief, Wockhardt USA LLC is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054. Wockhardt USA LLC is the U.S. agent of service for Wockhardt Bio AG. Upon information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Wockhardt Limited.

4. Upon information and belief, Wockhardt Limited is a corporation organized and existing under the laws of India, having its principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai, 400051, India.

NATURE OF THE ACTION

5. This is an action for infringement of 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 Wockhardt Bio AG’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, import, offer to sell and sell certain generic pharmaceutical products (“Wockhardt Bio AG’s generic products”) prior to the expiration of the asserted patent.

JURISDICTION AND VENUE

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

7. This Court has jurisdiction over Wockhardt Bio AG. Wockhardt Bio AG is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Wockhardt Bio AG, directly or through its U.S. agent Wockhardt USA LLC, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Wockhardt Bio AG purposefully has conducted and continues to conduct business, directly or through its U.S. agent Wockhardt USA LLC, in this judicial district, and this judicial district is a likely destination of Wockhardt Bio AG's generic products. Wockhardt Bio AG has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

8. This Court has jurisdiction over Wockhardt USA LLC. Upon information and belief, Wockhardt USA LLC has its principal place of business in New Jersey. Wockhardt USA LLC, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Wockhardt USA LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

9. This Court has jurisdiction over Wockhardt Limited. Upon information and belief, Wockhardt Limited, directly or through its subsidiaries Wockhardt Bio AG and Wockhardt USA LLC, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Wockhardt Limited has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

10. Upon information and belief, Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited operate as a single integrated business. Wockhardt Limited's website, <http://www.wockhardt.com/get-in-touch/international-offices.aspx>, indicates that international offices include Wockhardt Limited (global headquarters), Wockhardt USA LLC and Wockhardt Bio AG. Wockhardt USA LLC's website, http://www.wockhardtusa.com/about_us.html, states that "Wockhardt Limited created its US subsidiary Wockhardt USA in early 2004 with a modest portfolio . . . Wockhardt USA now represents more than 41% of Wockhardt Ltd's global business."

11. Upon information and belief, this Court additionally has jurisdiction over Wockhardt Limited, Wockhardt Bio AG and Wockhardt USA LLC because they have availed themselves of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated April 16, 2014, that "WOCKHARDT LTD., WOCKHARDT USA LLC, AND WOCKHARDT BIO AG (collectively "Wockhardt") hereby extend an offer of confidential access to Abbreviated New Drug Application number 205607 . . . This Agreement shall be governed in accordance with the laws of the state of New Jersey."

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

FIRST COUNT FOR PATENT INFRINGEMENT

13. The U.S. Patent and Trademark Office 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 A.

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

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

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

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

18. Otsuka lists the '760 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

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

20. Upon information and belief, Wockhardt Bio AG submitted ANDA No. 20-5607 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 Wockhardt Bio AG’s generic products in the United States. Otsuka received a letter from Wockhardt Bio AG dated April 16, 2014 (“Wockhardt Bio AG’s 20-5607 letter”), purporting to include a Notice of Certification for ANDA No. 20-5607 under 21 U.S.C. §§ 355(j)(2)(B)(ii) and (iv)(II) and 21 C.F.R. § 314.95(c)(6) as to the '760 patent.

22. Wockhardt Bio AG’s 20-5607 letter alleges that “[t]he established name of the proposed drug products that are the subject of Wockhardt’s ANDA is Aripiprazole Tablets.”

23. Upon information and belief, Wockhardt Bio AG’s generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

24. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Wockhardt Bio AG has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-5607 seeking approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG’s generic products before the expiration date of the '760 patent.

25. Upon information and belief, Wockhardt Bio AG's actions relating to Wockhardt Bio AG's ANDA No. 20-5607 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt 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), Wockhardt has infringed at least one claim of the '760 patent through Wockhardt Bio AG's submission of ANDA No. 20-5607 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products in the United States before the expiration of the '760 patent;
- 2) order that the effective date of any approval by the FDA of Wockhardt Bio AG'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;
- 3) enjoin Wockhardt from the manufacture, use, import, offer to sell and sale of Wockhardt Bio AG's generic products until the expiration of the '760 patent, or such later date as the Court may determine;
- 4) enjoin Wockhardt and all persons acting in concert with Wockhardt, from seeking, obtaining or maintaining approval of Wockhardt Bio AG's ANDA No. 20-5607 until the expiration of the '760 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.

Respectfully submitted,

s/ John F. Brenner

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