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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AJANTA PHARMA LIMITED, AJANTA PHARMA USA INC. and AUROBINDO PHARMA LIMITED, Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Ajanta Pharma Limited ("Ajanta Pharma Ltd."), Ajanta Pharma USA Inc. ("Ajanta Pharma USA") and Aurobindo Pharma Limited ("Aurobindo Pharma 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, Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at No. 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West) Mumbai, Maharashtra 400067 India.

3. Upon information and belief, Ajanta Pharma USA is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at One Grande Commons, 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807. Upon information and belief, Ajanta Pharma USA is a wholly-owned subsidiary of Ajanta Pharma Ltd.

4. Upon information and belief, Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad - 500 038, Andhra Pradesh, India.

NATURE OF THE ACTION

5. This is an action for infringement of U.S. Patent No. 9,089,567 ("the '567 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 Ajanta Pharma Ltd.'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, sell and offer to sell generic pharmaceutical products ("Defendants' 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 Ajanta Pharma Ltd. Upon information and belief, Ajanta Pharma Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Ajanta Pharma Ltd., directly or through its wholly-owned subsidiary, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Ajanta Pharma Ltd. purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Defendants' generic products. Upon information and belief, Ajanta Pharma Ltd. has five drug products approved by the FDA, "19 ANDAs [] under review" by the FDA as of November 2015, and expects the "US market to be [its] key growth driver in coming years." *See* http://www.ajantapharma.com/regulated-market.html. Upon information and belief, Ajanta Pharma Ltd.'s website states that "[i]n the next five year horizon, Ajanta plans to have a significant presence in the US." *See* http://www.ajantapharma.com/APUSAI.html. Ajanta Pharma Ltd. 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 initiated in this jurisdiction.

8. This Court has jurisdiction over Ajanta Pharma USA. Upon information and belief, Ajanta Pharma USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Ajanta Pharma USA, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Ajanta Pharma 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 Defendants'

generic products. According to its website, Ajanta Pharma USA provides "a dedicated front end sales and marketing team" in the United States marketplace. *See* http://ajantapharmausa.com/business-development.html. Upon information and belief, Ajanta Pharma USA is registered (No. 5004507) as a Drug Manufacturer in the State of New Jersey. Ajanta Pharma 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 actions initiated in this jurisdiction.

9. Upon information and belief, Ajanta Pharma Ltd. and Ajanta Pharma USA operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district. According to Ajanta Pharma USA's website, Ajanta Pharma Ltd. is "a fully-integrated specialty pharmaceutical company" focusing its research and development efforts in the United States market on "Immediate-Release, Extended-Release, Delayed-Release, Orally Disintegrating Tablets and Powders." *See* http://www.ajantapharmausa.com/overview.html. Upon information and belief, Ajanta Pharma Ltd.'s website states that "[c]ommercialization of [its] ANDAs in the US shall be done by [its] 100% owned subsidiary, Ajanta Pharma USA, Inc., which has its own sales and marketing team." *See* http://www.ajantapharma.com/APUSAI.html. Upon information and belief, Ajanta Pharma USA also acts as "an administrative office for liaisoning [sic]" with the FDA. *See* http://wwww.ajantapharma.com/Subsidiaries.html.

10. This Court has jurisdiction over Aurobindo Pharma Ltd. Upon information and belief, Aurobindo Pharma Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and

belief, Aurobindo Pharma Ltd., directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Aurobindo Pharma Ltd. 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 initiated in this jurisdiction, including in related civil action 14-cv-3306-JBS-KMW. Aurobindo Pharma Ltd. has previously admitted in other civil actions initiated in this jurisdiction that it sells and markets pharmaceutical products in the United States and in this judicial district.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

12. The U.S. Patent and Trademark Office ("PTO") issued the '567 patent on July 28, 2015, entitled "Method of Treating Cognitive Impairments and Schizophrenias." A copy of the '567 patent is attached as Exhibit A.

13. Otsuka is the owner of the '567 patent by virtue of assignment.

14. The '567 patent expires on January 28, 2022, subject to any supplemental patent term adjustment.

15. The '567 patent is directed to and claims, *inter alia,* methods of treatment of schizophrenia.

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

17. Otsuka lists the '567 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

18. Defendants have actual knowledge of the '567 patent.

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

20. Upon information and belief, Ajanta Pharma Ltd. submitted ANDA No. 206174 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 Defendants' generic products in the United States.

21. Otsuka received a letter from Ajanta Pharma Ltd. dated November 10, 2015 ("Ajanta Pharma Ltd.'s 206174 letter"), purporting to include a Notice of Certification for ANDA No. 206174 under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(c)(1) as to the '567 patent.

22. Ajanta Pharma Ltd.'s 206174 letter alleges that the established name of the drug products that are the subject of Ajanta Pharma Ltd.'s ANDA is "Aripiprazole Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg & 30 mg USP."

23. Upon information and belief, the manufacture, use, import, offer for sale and sale of Defendants' generic products will, if approved and marketed, directly infringe at least one claim of the '567 patent.

24. Upon information and belief, Defendants have taken active steps to intentionally induce infringement of the '567 patent.

25. Upon information and belief, Defendants have taken active steps to encourage the sale and use of Defendants' generic products by physicians, pharmacists and/or patients in accordance with the methods of treatment claimed in the '567 patent by providing information and instructions in its tablet package insert encouraging the use of aripiprazole in those methods of treatment.

26. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '567 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206174 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '567 patent.

27. Upon information and belief, Ajanta Pharma Ltd.'s actions relating to Ajanta Pharma Ltd.'s ANDA No. 206174 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Ajanta Pharma Ltd., Ajanta Pharma USA and Aurobindo Pharma 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), Defendants have infringed at least one claim of the '567 patent through Ajanta Pharma Ltd.'s submission of ANDA No. 206174 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '567 patent;

2) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '567 patent, or such later date as the Court may determine;

3) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '567 patent, or such later date as the Court may determine;

4) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Ajanta Pharma Ltd.'s ANDA No. 206174 until expiration of the '567 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/ Melissa Chuderewicz
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