UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Aurobindo Pharma Limited ("Aurobindo Pharma Ltd."), Aurobindo Pharma USA, Inc. ("Aurobindo USA") and Aurolife Pharma LLC ("Aurolife") (collectively, "Aurobindo"), 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, 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.

3. Upon information and belief, Aurobindo USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, NJ 08810. Upon information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Pharma Ltd.

4. Upon information and belief, Aurolife is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2400 Route 130 North, Dayton, NJ 08810. Upon information and belief, Aurolife is a wholly-owned subsidiary of Aurobindo USA.

NATURE OF THE ACTION

5. This is an action for infringement of U.S. Patent No. 8,759,350 ("the '350 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 Aurobindo 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, offer to sell and sell generic pharmaceutical products ("Aurobindo Pharma Ltd.'s generic products") before 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. Upon information and belief, this Court has jurisdiction over Aurobindo Pharma Ltd. 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 through its wholly-owned subsidiaries Aurobindo

USA and Aurolife, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Aurobindo Pharma Ltd. purposefully has conducted and continues to conduct business, directly or through its wholly-owned subsidiaries Aurobindo USA and Aurolife, in this judicial district, and this judicial district is a likely destination of Aurobindo Pharma Ltd.'s generic products. 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. Aurobindo Pharma Ltd. has previously admitted in other civil actions initiated in this jurisdiction that it sells and markets pharmaceutical products in the United Stated and in this judicial district.

8. Upon information and belief, this Court additionally has jurisdiction over Aurobindo Pharma Ltd. because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated September 17, 2014, that "[t]his Offer of Confidential Access shall be governed by the laws of the State of New Jersey."

9. Upon information and belief, this Court has jurisdiction over Aurobindo USA. Upon information and belief, Aurobindo USA has its principal place of business in New Jersey. Upon information and belief, Aurobindo USA, directly or indirectly, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. For example, Aurobindo USA is registered as a wholesaler in New Jersey. *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Aurobindo USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction. Upon information and belief,

Aurobindo Pharma Ltd.'s website, http://www.aurobindo.com/contact-us/reach-us, identifies Aurobindo USA as a place of contact for its Corporate Office. Aurobindo Pharma Ltd. has previously admitted in another civil action initiated in this jurisdiction that it is in the business of developing and manufacturing generic pharmaceutical products and that it sells and delivers its pharmaceutical products to Aurobindo USA in New Jersey.

10. Upon information and belief, this Court has jurisdiction over Aurolife. Upon information and belief, Aurolife has its principal place of business in New Jersey. Upon information and belief, Aurolife markets and sells products for Aurobindo Pharma Ltd. throughout the United States and in this judicial district. Upon information and belief, Aurolife markets and sells oral solid dosage forms for the treatment of disorders related to the central nervous system, including schizophrenia, throughout the United States and in this judicial district. Aurolife 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. Upon information and belief, Aurolife's website, http://aurolifepharma.com/aboutus.html, states that:

> Aurolife's goal is to become the leading US based generic pharmaceutical product manufacturer in the specialty and niche areas drug. Aurolife is targeted to obtain 100+ ANDA submissions, 70+ US FDA approved ANDAs and to manufacture and market 70+ products with 350+ dosage forms by the year 2014. Aurolife is a 100% owned subsidiary of Aurobindo Pharma USA, Inc. (APUSA) and is part of $700+ million strong Aurobindo group of companies . . . . Aurolife is exclusively created to address the US pharmaceutical manufacturing needs and to address market opportunities.

11. Upon information and belief, Aurobindo Pharma Ltd., Aurobindo USA and Aurolife hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products.

12. Upon information and belief, Aurobindo Pharma Ltd., Aurobindo USA and Aurolife 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.

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

FIRST COUNT FOR PATENT INFRINGEMENT

14. The U.S. Patent and Trademark Office ("PTO") issued the '350 patent on June 24, 2014, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors For Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit A.

15. Otsuka is the owner of the '350 patent by virtue of assignment.

16. The '350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

17. The '350 patent is directed to and claims, *inter alia,* compositions and methods of treatment.

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

19. Otsuka lists the '350 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

21. Upon information and belief, Aurobindo Pharma Ltd. submitted ANDA No. 20-3908 to the FDA, under Section 505(j), seeking approval to manufacture, use, import, offer to sell and sell Aurobindo Pharma Ltd.'s generic products in the United States.

22. Otsuka received a letter from Aurobindo Pharma Ltd. dated September 17, 2014, ("Aurobindo Pharma Ltd.'s letter") purporting to include a Notice of Certification for ANDA No. 20-3908 under 21 U.S.C. §§ 355(j)(2)(B)(ii)(I), (iv)(I) and (iv)(II); and 21 C.F.R. §§ 314.95(c)(1) and (c)(6)(i)-(ii) as to the '350 patent.

23. Aurobindo Pharma Ltd.'s letter alleges that Aurobindo Pharma Ltd.'s generic products are "aripiprazole oral tablets."

24. Upon information and belief, the manufacture, use, import, offer for sale and sale of Aurobindo Pharma Ltd.'s generic products will, if approved and marketed, infringe at least one claim of the '350 patent.

25. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-3908 seeking approval to manufacture, use, import, offer to sell and sell Aurobindo Pharma Ltd.'s generic products before the expiration date of the '350 patent.

26. Upon information and belief, Aurobindo Pharma Ltd.'s actions relating to Aurobindo Pharma Ltd.'s ANDA No. 20-3908 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Aurobindo Pharma Ltd., Aurobindo USA and Aurolife.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Aurobindo Pharma Ltd., Aurobindo USA and Aurolife 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), Aurobindo has infringed at least one claim of the '350 patent through Aurobindo Pharma Ltd.'s submission of ANDA No. 20-3908 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Aurobindo Pharma Ltd.'s generic products in the United States before the expiration of the '350 patent;

2) order that the effective date of any approval by the FDA of Aurobindo Pharma Ltd.'s generic products be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;

3) enjoin Aurobindo from the manufacture, use, import, offer for sale and sale of Aurobindo Pharma Ltd.'s generic products until the expiration of the '350 patent, or such later date as the Court may determine;

4) enjoin Aurobindo and all persons acting in concert with Aurobindo, from seeking, obtaining or maintaining approval of Aurobindo Pharma Ltd.'s ANDA No. 20-3908 until the expiration of the '350 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,

Dated: October 31, 2014

By: *s/ Melissa A. Chuderewicz*

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