UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. MACLEODS PHARMACEUTICALS LTD. AND MACLEODS PHARMA USA, INC., Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Macleods Pharmaceuticals Ltd. ("Macleods Pharmaceuticals") and Macleods Pharma USA, Inc. ("Macleods USA") (collectively "Macleods"), 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, Macleods Pharmaceuticals is a private corporation organized and existing under the laws of India, having a place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059.

3. Upon information and belief, Macleods USA is a private corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place

of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ 08536. Upon information and belief, Macleods USA is a wholly-owned subsidiary of Macleods Pharmaceuticals.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent No. 9,387,182 ("the '182 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 Macleods Pharmaceuticals 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, sell, offer to sell and import generic pharmaceutical products ("Macleods' generic products") prior to 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. This Court has jurisdiction over Macleods Pharmaceuticals. Upon information and belief, Macleods Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Macleods Pharmaceuticals, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Macleods Pharmaceuticals purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Macleods' generic products. Upon information and belief, Macleods Pharmaceuticals is a "truly . . . global pharmaceutical company." *See*

http://www.macleodspharma.com/default.asp. Upon information and belief, Macleods Pharmaceuticals' website states that "Macleods has received FDA approval on 9 [ANDAs] and has another 60 filed and awaiting approval." *See* http://www.macleodspharma.com/UnitedStates.asp.

7. This Court has jurisdiction over Macleods USA. Upon information and belief, Macleods USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Macleods USA, directly or indirectly, manufactures, imports, markets and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Macleods USA is registered as a wholesaler in the State of New Jersey (No. 5004370). *See* New Jersey Registration and Verification, at http://web.doh.state.nj.us/apps2FoodDrugLicense/fdList.aspx.

8. Upon information and belief, Macleods Pharmaceuticals and Macleods 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. Upon information and belief, Macleods Pharmaceuticals is "a vertically integrated global pharmaceutical company" with "more than 10,000 professionally qualified employees across the globe." *See* http://www.macleodspharma.com/default.asp.

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

FIRST COUNT FOR PATENT INFRINGEMENT

1. The U.S. Patent and Trademark Office ("PTO") issued the '182 patent on July 12, 2016, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '182 patent is attached as Exhibit A.

2. Otsuka is the owner of the '182 patent by virtue of assignment.

3. The '182 patent expires on December 25, 2023, excluding any pediatric exclusivity.

4. The '182 patent is directed to and claims, inter alia, pharmaceutical compositions and methods of treatment.

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

6. Otsuka lists the '182 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

8. Upon information and belief, Macleods Pharmaceuticals submitted ANDA No. 204111 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 ("Macleods' generic products") in the United States.

9. Otsuka received a letter from Macleods Pharmaceuticals dated August 11, 2016, ("Macleods' letter"), purporting to include a Notice of Certification for ANDA No. 204111 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(6) as to the '182 patent.

10. Macleods' letter alleges that it seeks to obtain approval to "engage in the commercial manufacture, use, importation, offer for sale and sale of Macleods' 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg of aripiprazole tablets."

11. Upon information and belief, Macleods' generic products will, if approved and marketed, infringe at least one claim of the '182 patent.

12. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods Pharmaceuticals has infringed at least one claim of the '182 patent by submitting, or causing to be submitted to the FDA, ANDA No. 204111 seeking approval to manufacture, use, import, offer to sell and sell Macleods' generic products before the expiration date of the '182 patent.

13. Upon information and belief, Macleods Pharmaceuticals' actions relating to ANDA No. 204111 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Macleods Pharmaceuticals and Macleods USA.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Macleods 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), Macleods has infringed at least one claim of the '182 patent through Macleods Pharmaceuticals' submission of ANDA No. 204111 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Macleods' generic products in the United States before the expiration of the '182 patent;

2) order that the effective date of any approval by the FDA of Macleods' generic products be a date that is not earlier than the expiration of the '182 patent, or such later date as the Court may determine;

3) enjoin Macleods from the manufacture, use, import, offer for sale and sale of Macleods' generic products until the expiration of the '182 patent, or such later date as the Court may determine;

4) enjoin Macleods and all persons acting in concert with Macleods from seeking, obtaining or maintaining approval of Macleods Pharmaceuticals' ANDA No. 204111 until expiration of the '182 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,

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