

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

V.

ALKEM LABORATORIES LIMITED,  
ASCEND LABORATORIES, LLC and  
ALEMBIC PHARMACEUTICALS  
LIMITED,

Defendants.

Civil Action No.:

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Alkem Laboratories Ltd. (“Alkem”), Ascend Laboratories, LLC (“Ascend”) and Alembic Pharmaceuticals Limited (“Alembic”) (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, Alkem is a corporation organized and existing under the laws of India, having its principal place of business at Alkem House, Devashish, Senapati Bapat Road, Lower Parel, Mumbai, 400013 India.

3. Upon information and belief, Ascend is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 180 Summit Avenue, Suite 200, Montvale, NJ 07645.

4. Upon information and belief, Alembic is a corporation organized and existing under the laws of India, having its principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

### **NATURE OF THE ACTION**

5. This is an action for infringement of U.S. Patent No. 9,359,302 (“the ’302 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 Alkem 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, sell, offer to sell and import 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 Alkem. Upon information and belief, Alkem is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Alkem, directly or through its subsidiaries, affiliates and/or agents, including Ascend, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. *See, e.g.*, <http://www.capitalmarket.com/pub/dp/dp19299.pdf> (“With respect to the United States, we manufacture and sell products in this market . . . Our ability to achieve continued growth and profitability through sales of generic pharmaceuticals is dependent on our success in challenging

patents[.]”). Alkem 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. Upon information and belief, this Court additionally has jurisdiction over Alkem because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated August 12, 2016, that “[t]his Agreement shall be governed in accordance with the laws of the state of New Jersey without regard to its conflict-of-law rules.”

9. This Court has jurisdiction over Ascend. Upon information and belief, Ascend is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Ascend, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Ascend is a distributor of Defendants’ generic products throughout the United States and in this judicial district. Upon information and belief, Ascend 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, Ascend is registered to do business in New Jersey under Business I.D. No. 0600158194. Upon information and belief, Ascend is registered as a Manufacturer and Wholesaler in the State of New Jersey (No. 5003567) under the trade name “Ascend Laboratories, LLC.” *See* New Jersey Drug Registration and Verification, at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx>. Ascend has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in another civil action initiated in this jurisdiction.

10. Upon information and belief, Alkem and Ascend 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 Alkem's website, it "owns and operates 14 manufacturing facilities across five locations in India and two manufacturing facilities in the United States." *See* <http://www.alkemlabs.com/manufacturing-facilities>

11. This Court has jurisdiction over Alembic. Upon information and belief, Alembic is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Alembic, directly or indirectly, manufactures, markets and sells generic drug products throughout the United States and this judicial district. Upon information and belief, Alembic maintains continuous and systematic contacts with New Jersey through its wholly owned subsidiary Alembic Pharmaceuticals Inc., located at 116 Village Boulevard, Suite 200, Princeton, NJ 08650. Upon information and belief, Alembic is a supplier of aripiprazole drug substance. *See* [www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/UCM370723.txt](http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/UCM370723.txt). Alembic 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.

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

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**FIRST COUNT FOR PATENT INFRINGEMENT**

13. The U.S. Patent and Trademark Office (“PTO”) issued the ’302 patent on June 7, 2016, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’302 patent is attached as Exhibit A.

14. Otsuka is the owner of the ’302 patent by virtue of assignment.

15. The ’302 patent expires on September 25, 2022, excluding any pediatric exclusivity.

16. The ’302 patent is directed to and claims, *inter alia*, aripiprazole crystals, pharmaceutical compositions and methods of treatment.

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 ’302 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, Alkem submitted ANDA No. 207105 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 Alkem dated August 12, 2016, purporting to include a Notice of Certification for ANDA No. 207105 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) (“Alkem’s letter”) as to the ’302 patent.

22. Alkem’s letter alleges that the name of the drug product that is subject of the Alkem’s ANDA is “aripiprazole tablets (2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg).”

23. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '302 patent.

24. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alkem has infringed at least one claim of the '302 patent by submitting, or causing to be submitted to the FDA, ANDA No. 207105 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '302 patent.

25. Upon information and belief, Alkem's actions relating to Alkem's ANDA No. 207105 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Alkem, Ascend and Alembic.

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Alkem 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), Alkem has infringed at least one claim of the '302 patent through Alkem Laboratories Ltd.'s submission of ANDA No. 207105 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 '302 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 '302 patent, or such later date as the Court may determine;
- 3) enjoin Alkem from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '302 patent, or such later date as the Court may determine;

- 4) enjoin Alkem and all persons acting in concert with Alkem from seeking, obtaining or maintaining approval of Alkem's ANDA No. 207105 until expiration of the '302 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 A. Chuderewicz  
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