

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
ALKEM LABORATORIES LIMITED,)	
ASCEND LABORATORIES, LLC and)	
ALEMBIC PHARMACEUTICALS)	
LIMITED,)	
)	
Defendants.)	

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. 8,017,615 (“the ’615 patent”), U.S. Patent No. 8,580,796 (“the ’796 patent”) and 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 Alkem’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 (“Defendants’ generic products”) prior to the expiration of the asserted patents.

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 October 13, 2015, 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 "has . . . grown over the last 4 decades, with . . . subsidiaries and marketing offices located across the globe." *See* <http://www.alkemlabs.com/infrastructure>.

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. 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).

FIRST COUNT FOR PATENT INFRINGEMENT

13. The U.S. Patent and Trademark Office (“PTO”) issued the ’615 patent on September 13, 2011, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’615 patent is attached as Exhibit A.

14. Otsuka is the owner of the ’615 patent by virtue of assignment.

15. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

16. The ’615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations, and processes for preparing pharmaceutical solid oral preparations.

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 ’615 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 October 13, 2015, 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 207105 letter”) as to the ’615 patent.

22. Alkem’s 207105 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 '615 patent.

24. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alkem has infringed at least one claim of the '615 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 '615 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.

SECOND COUNT FOR PATENT INFRINGEMENT

26. Otsuka realleges, and incorporates in full herein, paragraphs 17-22.

27. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

28. Otsuka is the owner of the '796 patent by virtue of assignment.

29. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

30. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

31. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

32. Alkem's 207105 letter purports to include a Notice of Certification for ANDA No. 207105 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) as to the '796 patent.

33. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

34. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alkem has infringed at least one claim of the '796 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 '796 patent.

35. 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.

THIRD COUNT FOR PATENT INFRINGEMENT

36. Otsuka realleges, and incorporates in full herein, paragraphs 17-22.

37. The PTO 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 C.

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

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

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

41. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

42. Alkem's 207105 letter purports to include a Notice of Certification for ANDA No. 207105 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) as to the '760 patent.

43. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

44. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alkem has infringed at least one claim of the '760 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 '760 patent.

45. 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 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 '615 patent through Alkem'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 '615 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 '615 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 '615 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 Alkem's ANDA No. 207105 until expiration of the '615 patent;

- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '796 patent through Alkem'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 '796 patent;
- 6) 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 '796 patent, or such later date as the Court may determine;
- 7) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 8) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Alkem's ANDA No. 207105 until expiration of the '796 patent;
- 9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Alkem'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 '760 patent;
- 10) 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 '760 patent, or such later date as the Court may determine;

- 11) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '760 patent, or such later date as the Court may determine;
- 12) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Alkem's ANDA No. 207105 until expiration of the '760 patent;
- 13) 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
- 14) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

s/ Melissa Chuderewicz
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