UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AJANTA PHARMA LIMITED and AJANTA PHARMA USA INC., 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.") and Ajanta Pharma USA Inc. ("Ajanta Pharma USA") (collectively "Ajanta"), 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 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.

NATURE OF THE ACTION

4. 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 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, sell, offer to sell and import generic pharmaceutical products ("Ajanta Pharma Ltd.'s generic products") prior to the expiration of the asserted patents.

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 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 the likely

destination of Ajanta Pharma Ltd.'s generic products. Upon information and belief, Ajanta Pharma Ltd. has two drug products approved by the FDA, "23 ANDAs [] under review" by the FDA as of June 2014, 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 present in the US." *See* http://www.ajantapharma.com/APUSAI.html.

7. 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 Ajanta Pharma Ltd.'s 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 has 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 registered (No. 5004507) as a Drug Manufacturer in the State of New Jersey.

8. 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://www.ajantapharma.com/Subsidiaries.html.

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

10. 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.

11. Otsuka is the owner of the '615 patent by virtue of assignment.

12. The '615 patent expires on December 16, 2024 (including pediatric exclusivity).

13. The '615 patent is directed to and claims, *inter alia,* pharmaceutical solid oral preparations, as well as processes for preparing pharmaceutical solid oral preparations.

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

15. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

17. 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 Ajanta Pharma Ltd.'s generic products in the United States.

18. Otsuka received a letter from Ajanta Pharma Ltd. dated August 5, 2014, purporting to include a Notice of Certification for ANDA No. 206174 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("Ajanta Pharma Ltd.'s 206174 letter") as to the '615 patent.

19. Ajanta Pharma Ltd.'s 206174 letter alleges that the name of the drug product that is subject of the Ajanta Pharma Ltd. ANDA is Aripiprazole Tablets 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg for oral administration.

20. Upon information and belief, Ajanta Pharma Ltd.'s generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

21. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta Pharma Ltd. has infringed at least one claim of the '615 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 Ajanta Pharma Ltd.'s generic products before the expiration date of the '615 patent.

22. Upon information and belief, Ajanta Pharma Ltd.'s actions relating to ANDA No. 206174 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Ajanta Pharma Ltd. and Ajanta Pharma USA.

SECOND COUNT FOR PATENT INFRINGEMENT

23. Otsuka realleges, and incorporates in full herein, paragraphs 14–19.

24. 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.

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

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

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

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

29. Ajanta Pharma Ltd.'s 206174 letter purports to include a Notice of Certification for ANDA No. 206174 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent.

30. Upon information and belief, Ajanta Pharma Ltd.'s generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

31. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta Pharma Ltd. has infringed at least one claim of the '796 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 Ajanta Pharma Ltd.'s generic products before the expiration date of the '796 patent.

32. Upon information and belief, Ajanta Pharma Ltd.'s actions relating to ANDA No. 206174 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Ajanta Pharma Ltd. and Ajanta Pharma USA.

THIRD COUNT FOR PATENT INFRINGEMENT

33. Otsuka realleges, and incorporates in full herein, paragraphs 14–19.

34. 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.

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

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

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

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

39. Ajanta Pharma Ltd.'s 206174 letter purports to include a Notice of Certification for ANDA No. 206174 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent.

40. Upon information and belief, Ajanta Pharma Ltd.'s generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

41. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta Pharma Ltd. has infringed at least one claim of the '760 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 Ajanta Pharma Ltd.'s generic products before the expiration date of the '760 patent.

42. Upon information and belief, Ajanta Pharma Ltd.'s actions relating to ANDA No. 206174 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Ajanta Pharma Ltd. and Ajanta Pharma USA.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Ajanta Pharma Ltd. and Ajanta Pharma USA 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), Ajanta has infringed at least one claim of the '615 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 Ajanta Pharma Ltd.'s 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 Ajanta Pharma Ltd.'s 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 Ajanta from the manufacture, use, import, offer for sale and sale of Ajanta Pharma Ltd.'s generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin Ajanta and all persons acting in concert with Ajanta, from seeking, obtaining or maintaining approval of Ajanta Pharma Ltd.'s ANDA No. 206174 until expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed at least one claim of the '796 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 Ajanta Pharma Ltd.'s 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 Ajanta Pharma Ltd.'s 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 Ajanta from the manufacture, use, import, offer for sale and sale of Ajanta Pharma Ltd.'s generic products until the expiration of the '796 patent, or such later date as the Court may determine;

8) enjoin Ajanta and all persons acting in concert with Ajanta, from seeking, obtaining or maintaining approval of Ajanta Pharma Ltd.'s ANDA No. 206174 until expiration of the '796 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed at least one claim of the '760 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 Ajanta Pharma Ltd.'s 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 Ajanta Pharma Ltd.'s 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 Ajanta from the manufacture, use, import, offer for sale and sale of Ajanta Pharma Ltd.'s generic products until the expiration of the '760 patent, or such later date as the Court may determine;

12) enjoin Ajanta and all persons acting in concert with Ajanta, from seeking, obtaining or maintaining approval of Ajanta Pharma Ltd.'s ANDA No. 206174 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 A. Chuderewicz
Melissa A. Chuderewicz
chuderem@pepperlaw.com
PEPPER HAMILTON LLP
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543
(609) 452-0808
Attorney for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

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Of counsel:

James B. Monroe
Paul W. Browning
Denise Main
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000