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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AJANTA PHARMA LIMITED, AJANTA PHARMA USA INC. and AUROBINDO PHARMA LIMITED, Defendants.	Civil Action No.: 14-cv-5876-JBS-KMW

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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

4. Upon information and belief, Aurobindo Pharma Limited 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.

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"), U.S. Patent No. 8,642,760 ("the '760 patent") and 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, and for a declaratory judgment of infringement of the '350 patent under 28 U.S.C. §§ 2201 and 2202. 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 ("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, 1338(a), 2201 and 2202.

7. 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 Defendants' 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. Ajanta Pharma Ltd. has consented to personal jurisdiction in this judicial district for purposes of this action. (D.I. 8 at 3.)

8. 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 Defendants' 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. Ajanta Pharma USA has consented to personal jurisdiction in this judicial district for purposes of this action. (D.I. 8 at 4.)

9. 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.

10. This Court has jurisdiction over Aurobindo Pharma Ltd. Upon information and belief, 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 indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and this judicial district. 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, including in related civil action 14-cv-3306-JBS-KMW. Aurobindo Pharma Ltd. has previously admitted in other civil actions initiated in this jurisdiction that it sells and markets pharmaceutical products in the United States and in this judicial district.

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

FIRST COUNT FOR PATENT INFRINGEMENT

12. 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.

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

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

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

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

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

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

19. 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 Defendants' generic products in the United States.

20. 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.

21. 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.

22. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have 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 Defendants' generic products before the expiration date of the '615 patent.

24. 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., Ajanta Pharma USA and Aurobindo Pharma Ltd.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

26. 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.

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

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

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

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

31. 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.

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

33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have 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 Defendants' generic products before the expiration date of the '796 patent.

34. 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., Ajanta Pharma USA and Aurobindo Pharma Ltd.

THIRD COUNT FOR PATENT INFRINGEMENT

35. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

36. 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.

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

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

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

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

41. 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.

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

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have 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 Defendants' generic products before the expiration date of the '760 patent.

44. 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., Ajanta Pharma USA and Aurobindo Pharma Ltd.

FOURTH COUNT FOR PATENT INFRINGEMENT

45. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

46. The 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 D.

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

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

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

50. Otsuka lists the '350 patent in the Orange Book for NDA No. 21-436.

51. Upon information and belief, Defendants have actual knowledge of the '350 patent.

52. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '350 patent.

53. Upon information and belief, the label for Defendants' generic products will recommend, suggest, encourage and/or instruct others to use Defendants' generic products in a manner that infringes at least one claim of the '350 patent.

54. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '350 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 Defendants' generic products before the expiration date of the '350 patent.

55. 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., Ajanta Pharma USA and Aurobindo Pharma Ltd.

FIFTH COUNT FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

56. Otsuka realleges, and incorporates in full herein, paragraphs 16-21 and 46-55.

57. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

58. There is an actual and justiciable controversy between Otsuka and Defendants concerning infringement of the '350 patent of sufficient immediacy and reality such that the Court may entertain Otsuka's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

59. Defendants have made, and continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants' generic products prior to expiration of the '350 patent.

60. Defendants' actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 206174 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '350 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '350 patent and acts by Otsuka.

61. Upon information and belief, the FDA may approve ANDA No. 206174 as early as the April 20, 2015, expiration of the Pediatric Exclusivity period associated with U.S. Patent No. 5,006,528.

62. Upon information and belief, Defendants intend to manufacture, use, offer for sale, sell and/or import Defendants' generic products upon FDA approval of ANDA No. 206174.

63. Any commercial manufacture, use, offer for sale, sale and/or importation of Defendants' generic products prior to the expiration of the '350 patent will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent under 35 U.S.C. §§ 271(a)-(c).

64. Otsuka will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

65. Otsuka does not have an adequate remedy at law.

66. Otsuka is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Defendants' generic products prior to expiration of the '350 patent by Defendants will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent.

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 Ajanta Pharma Ltd.'s submission of ANDA No. 206174 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 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), Defendants have 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 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 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), Defendants have 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 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 Ajanta Pharma Ltd.'s ANDA No. 206174 until expiration of the '760 patent;

13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '350 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 Defendants' generic products in the United States before the expiration of the '350 patent;

14) 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 '350 patent, or such later date as the Court may determine;

15) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '350 patent, or such later date as the Court may determine;

16) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Ajanta Pharma Ltd.'s ANDA No. 206174 until expiration of the '350 patent;

17) declare and enter judgment under 28 U.S.C. §§ 2201 and 2202 that any future commercial manufacture, use, offer for sale, sale and/or importation of Defendants' generic products prior to expiration of the '350 patent by Defendants will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent under 35 U.S.C. §§ 271(a)-(c);

18) order that, if Defendants engage in the commercial manufacture, use, sale, offer for sale or importation of Defendants' generic products before the expiration of the '350 patent, a judgment be awarded to Otsuka for damages resulting from such infringement, together with interest, in an amount to be determined at trial;

19) 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

20) award Otsuka such further and additional relief as this Court deems just and proper.

Date: April 7, 2015

Respectfully submitted,

s/ Melissa A. Chuderewicz
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