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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. APOTEX CORP., APOTEX INC. and HETERO LABS LIMITED, Defendants.	Civil Action No.: 14-cv-8074-JBS-KMW

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Apotex Corp., Apotex Inc. and Hetero Labs Limited (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, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L IT9.

4. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500 018, 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. This action relates to Apotex Inc.'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, as well as Defendants' actual manufacture, use, sale, offer for sale and import of Defendants' generic products upon approval of its ANDAs.

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 Apotex Corp. Upon information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Apotex Corp., directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Corp. "boast[s] over a billion dollars in sales—and a new ranking in the top 10 generic pharmaceutical companies according to recent IMS HEALTH data." http://www.apotex.com/us/en/about/apocorp_leader_july_2013.pdf. Upon information and belief, Apotex Corp. is registered in the State of New Jersey (No. 5003192) as a drug Wholesaler. Apotex Corp. 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. This Court has jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Inc., directly or through its subsidiaries, affiliates and/or agents, including Apotex Corp., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Inc. purposefully has conducted and continues to conduct business, directly or through its subsidiaries, affiliates and/or agents, including Apotex Corp., in this judicial district and this judicial district is a likely destination of Defendants' generic products. Upon information and belief, Apotex Inc. and Apotex Corp. share

a common corporate director. Apotex Inc. 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.

9. Upon information and belief, Apotex Corp. and Apotex Inc. 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, Apotex Inc. describes Apotex Inc. and its affiliates as a "vertically integrated company" with a "preference . . . to develop, manufacture and market [its] own products – from API to finished dosage form to marketing and distribution." *See* http://www.apotex.com/global/bd/namerica.asp.

10. This Court has jurisdiction over Hetero Labs Limited. Upon information and belief, Hetero Labs Limited is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Labs Limited, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Limited maintains continuous and systematic contacts with New Jersey through its authorized U.S. agent, PharmaQ, Inc., located at Waterview Plaza, 2001 Route 46, Suite 105, Parsippany, NJ 07054-1315. Hetero Labs Limited 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.

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, and 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, Apotex Inc. submitted ANDA No. 78-583 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 Apotex Inc. dated November 12, 2014, purporting to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) ("Apotex Inc.'s 78-583 letter") as to the '615 patent.

21. Apotex Inc.'s 78-583 letter alleges that the name of the drug product that is subject of the Apotex Inc. ANDA is "Aripiprazole Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg."

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), Apotex Inc. has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 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, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Hetero Labs Limited.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 12-24.

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. Apotex Inc.'s 78-583 letter purports to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '796 patent.

32. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe claims 1-2 of the '796 patent.

33. Upon information and belief, Defendants' generic products contain Anhydrous Aripiprazole Crystals B of low hygroscopicity as claimed in the '796 patent.

34. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed claims 1-2 of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 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, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Hetero Labs Limited.

THIRD COUNT FOR PATENT INFRINGEMENT

36. Otsuka realleges, and incorporates in full herein, paragraphs 25-35.

37. Apotex Inc.'s ANDA No. 78-583 was approved by the FDA on July 24, 2015.

38. Upon information and belief, Defendants are currently manufacturing, marketing, importing, using, selling and offering for sale Defendants' generic products in connection with ANDA No. 78-583.

39. Upon information and belief, Defendants are infringing claims 1-2 of the '796 patent under 35 U.S.C. § 271(a) by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products.

FOURTH COUNT FOR PATENT INFRINGEMENT

40. Otsuka realleges, and incorporates in full herein, paragraphs 12-24.

41. 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.

42. Otsuka is the owner of the ’760 patent by virtue of assignment.

43. The ’760 patent expires on March 25, 2023 (including pediatric exclusivity).

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

45. Otsuka lists the ’760 patent in the Orange Book for NDA No. 21-436.

46. Apotex Inc.’s 78-583 letter purports to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the ’760 patent.

47. Upon information and belief, Defendants’ generic products will, if approved and marketed, infringe claims 1-2 of the ’760 patent.

48. Defendants’ generic products contain aripiprazole as the drug substance, as shown in the approved labeling for Defendants’ generic products. *See* http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=569f1c32-fb6f-c34f-0894-4b1e7b744a8a (accessed January 8, 2016).

49. Upon information and belief, the aripiprazole drug substance contained in Defendants’ generic products are of low hygroscopicity as claimed in the ’760 patent.

50. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed claims 1-2 of the ’760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 seeking approval to manufacture, use, import, offer to sell and sell Defendants’ generic products before the expiration date of the ’760 patent.

51. Upon information and belief, Apotex Inc.’s actions relating to Apotex Inc.’s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Hetero Labs Limited.

FIFTH COUNT FOR PATENT INFRINGEMENT

52. Otsuka realleges, and incorporates in full herein, paragraphs 40-51.

53. Apotex Inc.'s ANDA No. 78-583 was approved by the FDA on July 24, 2015.

54. Upon information and belief, Defendants are currently manufacturing, marketing, importing, using, selling and offering for sale Defendants' generic products in connection with ANDA No. 78-583.

55. Upon information and belief, Defendants are infringing claims 1-2 of the '760 patent under 35 U.S.C. § 271(a) by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products.

SIXTH COUNT FOR PATENT INFRINGEMENT

56. Otsuka realleges, and incorporates in full herein, paragraphs 12-24.

57. 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.

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

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

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

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

62. Apotex Inc.'s 78-583 letter purports to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '350 patent.

63. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe claims 1-18 of the '350 patent.

64. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed claims 1-18 of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration of the '350 patent.

65. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Hetero Labs Limited.

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 Apotex Inc.'s submission of ANDA No. 78-583 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 Apotex Inc.'s ANDA No. 78-583 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 Apotex Inc.'s submission of ANDA No. 78-583 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 Apotex Inc.'s ANDA No. 78-583 until expiration of the '796 patent;

9) enter judgment that, under 35 U.S.C. § 271(a), Defendants have infringed at least one claim of the '796 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '796 patent;

10) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '796 patent by the

manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;

11) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Apotex Inc.'s submission of ANDA No. 78-583 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;

12) 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;

13) 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;

14) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 78-583 until expiration of the '760 patent;

15) enter judgment that, under 35 U.S.C. § 271(a), Defendants have infringed at least one claim of the '760 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '760 patent;

16) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '760 patent by the

manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;

17) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '350 patent through Apotex Inc.'s submission of ANDA No. 78-583 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; 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;

18) 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;

19) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 78-583 until expiration of the '350 patent;

20) find Defendants' infringement to have been willful and award Otsuka enhanced damages for this willful infringement;

21) 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

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

Date: March 23, 2016

Respectfully submitted,

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