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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. SCIEGEN PHARMACEUTICALS INC., BACTOLAC PHARMACEUTICAL, INC. and HETERO LABS LIMITED, Defendants.	Civil Action No.: 14-cv-8077 (JBS) (KMW)

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants ScieGen Pharmaceuticals Inc. ("ScieGen Pharmaceuticals"), Bactolac Pharmaceutical, Inc. ("Bactolac") (collectively "ScieGen") 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, ScieGen Pharmaceuticals is a private corporation organized and existing under the laws of the State of New York, having a place of business at 20 Davids Drive, Hauppauge, NY 11788. Upon information and belief, ScieGen Pharmaceuticals is a wholly owned subsidiary of Bactolac.

3. Upon information and belief, Bactolac is a private corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 7 Oser Avenue, Hauppauge, NY 11788.

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, and for a declaratory judgment of infringement of the '350 patent under 28 U.S.C. §§ 2201 and 2202. This action relates to ScieGen Pharmaceuticals' 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, 1338(a), 2201 and 2202.

7. This Court has jurisdiction over ScieGen Pharmaceuticals. Upon information and belief, ScieGen Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, ScieGen Pharmaceuticals, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. ScieGen Pharmaceuticals' "core business is in the areas of Development, Manufacturing, Marketing and Distribution of high quality and cost effective generic pharmaceutical products. ScieGen has robust product development pipeline and filed a couple of ANDA's [sic]. [ScieGen Pharmaceuticals] aim[s] to provide healthcare at economical prices to make this a healthier world to live in." *See* http://www.sciegenpharm.com/. Upon information and belief, ScieGen Pharmaceuticals 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.

8. This Court has jurisdiction over Bactolac. Upon information and belief, Bactolac is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Bactolac, directly or through its subsidiaries, including ScieGen Pharmaceuticals, manufactures, markets, imports, and sells generic drug products throughout the United States and in this judicial district.

9. Upon information and belief, ScieGen Pharmaceuticals and Bactolac 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, ScieGen Pharmaceuticals and Bactolac share at least two corporate officers.

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 Water View Plaza, 2001 Route 46, Suite 405, 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, ScieGen Pharmaceuticals submitted ANDA No. 20-6383 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 ScieGen Pharmaceuticals dated November 7, 2014, purporting to include a Notice of Certification for ANDA No. 20-6383 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("ScieGen Pharmaceuticals' 20-6383 letter") as to the '615 patent.

21. ScieGen Pharmaceuticals' 20-6383 letter alleges that "the established name of the Proposed ScieGen Product, as defined in § 502(e)(3) of the Act, is 'Aripiprazole Tablets'."

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. 20-6383 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, ScieGen Pharmaceuticals' actions relating to ScieGen Pharmaceuticals' ANDA No. 20-6383 complained of herein were done with the

cooperation, participation, assistance, and for the benefit, of ScieGen Pharmaceuticals, Bactolac and Hetero Labs Limited.

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. ScieGen Pharmaceuticals' 20-6383 letter purports to include a Notice of Certification for ANDA No. 20-6383 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. 20-6383 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, ScieGen Pharmaceuticals' actions relating to ScieGen Pharmaceuticals' ANDA No. 20-6383 complained of herein were done with the

cooperation, participation, assistance, and for the benefit, of ScieGen Pharmaceuticals, Bactolac and Hetero Labs Limited.

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. ScieGen Pharmaceuticals' 20-6383 letter purports to include a Notice of Certification for ANDA No. 20-6383 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. 20-6383 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, ScieGen Pharmaceuticals' actions relating to ScieGen Pharmaceuticals' ANDA No. 20-6383 complained of herein were done with the

cooperation, participation, assistance, and for the benefit, of ScieGen Pharmaceuticals, Bactolac and Hetero Labs Limited.

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, ScieGen has 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. 20-6383 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, ScieGen Pharmaceuticals' actions relating to ScieGen Pharmaceuticals' ANDA No. 20-6383 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of ScieGen Pharmaceuticals, Bactolac and Hetero Labs Limited.

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. 20-6383 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 ScieGen's ANDA No. 20-6383 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 promptly upon FDA approval of ANDA No. 20-6383.

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 the expiration of the '350 patent 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 ScieGen Pharmaceuticals' submission of ANDA No. 20-6383 to the FDA to obtain approval to manufacture, use, 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 ScieGen Pharmaceuticals' ANDA No. 20-6383 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 ScieGen Pharmaceuticals' submission of ANDA No. 20-6383 to the FDA to obtain approval to manufacture, use, 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 ScieGen Pharmaceuticals' ANDA No. 20-6383 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 ScieGen Pharmaceuticals' submission of ANDA No. 20-6383 to the FDA to obtain approval to manufacture, use, 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 ScieGen Pharmaceuticals' ANDA No. 20-6383 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 ScieGen Pharmaceuticals' submission of ANDA No. 20-6383 to the FDA to obtain approval to manufacture, use, 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 ScieGen Pharmaceuticals' ANDA No. 20-6383 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 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);

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.

Respectfully submitted,

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