UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. HETERO DRUGS LIMITED, HETERO LABS LIMITED and HETERO USA, INC. Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Hetero Drugs Limited, Hetero Labs Limited and Hetero USA, Inc. (collectively, "Hetero"), 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, Hetero Drugs Limited is a corporation organized and existing under the laws of India, having a place of business at 7-2-A2 Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, India. Upon information and belief, Hetero Drugs Limited is the parent corporation of Hetero Labs Limited.

3. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Andhra Pradesh, India.

4. Upon information and belief, Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Upon information and belief, Hetero USA, Inc. is a subsidiary of Hetero Labs Limited.

NATURE OF THE ACTION

5. This is an action for infringement of 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 Hetero USA, 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, sell and offer to sell generic pharmaceutical products ("Hetero's 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 Hetero Drugs Limited. Upon information and belief, Hetero Drugs Limited is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Drugs Limited, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. According to its website,

"Hetero is manufacturing [sic] product portfolio of over 200 products in major therapeutic areas, with an emphasis on . . . antidepressants/antipsychotics . . . ." *See* http://heterodrugs.com/busin-finished-dosages.shtml. And "Hetero exports its products across different regions [sic] USA, Canada, Europe, Japan . . . ." *See* http://heterodrugs.com/abt-globalpresence.shtml. Upon information and belief, Hetero Drugs Limited has submitted, or caused to be submitted, at least 50 ANDAs. *See* http://pharmaboardroom.com/interviews/interview-with-dr-bandi-parthasaradhi-reddy-hetero-drugs-limited/.

8. 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. Upon information and belief, Hetero Labs Limited is the Drug Master File holder for the aripiprazole active pharmaceutical ingredient used in Hetero's generic products. 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.

9. This Court has jurisdiction over Hetero USA, Inc. Upon information and belief, Hetero USA, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero USA, Inc., directly or indirectly, manufactures, imports, markets and sells generic drugs

throughout the United States and in this judicial district. Upon information and belief, Hetero USA, Inc. purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Hetero's generic products. Upon information and belief, Hetero USA, Inc. is registered to do business in New Jersey under Business I.D. No. 0400362826. Upon information and belief, Hetero USA, Inc. is registered as a Wholesaler in the State of New Jersey (No. 5004050) under the trade name "Hetero USA, Inc." *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Hetero USA, 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.

10. Upon information and belief, Hetero Drugs Limited, Hetero Labs Limited and Hetero USA, Inc. operate as a single integrated business. According to its website, "Hetero is building on the strengths of vertical integration in discovery research, process chemistry, API manufacturing, formulation development and commercialization." *See* http://www.heterodrugs.com/abt-overview.shtml. Upon information and belief, Hetero Drugs Limited and Hetero Labs Limited share common corporate directors.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

12. The U.S. Patent and Trademark Office ("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 A.

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

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

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

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 '796 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, Hetero USA, Inc. submitted ANDA No. 205064 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, offer to sell and sell Hetero's generic products in the United States.

20. Otsuka received a letter from Hetero USA, Inc. dated November 24, 2014, purporting to include a Notice of Certification for ANDA No. 205064 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("Hetero's '796 letter") as to the '796 patent.

21. Hetero's '796 letter alleges that the established name of the drug product that is the subject of Hetero USA, Inc.'s ANDA is "aripiprazole tablets (2mg, 5mg, 10mg, 15mg, 20mg and 30mg)."

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

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero USA, Inc. has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205064 seeking approval to manufacture, use, offer to sell and sell Hetero's generic products before the expiration date of the '796 patent.

24. Upon information and belief, Hetero USA, Inc.'s actions relating to Hetero USA, Inc.'s ANDA No. 205064 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Hetero Drugs Limited, Hetero Labs Limited and Hetero USA, Inc.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 16-19.

26. 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 B.

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

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

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

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

31. Otsuka received a letter from Hetero USA, Inc. dated November 24, 2014, purporting to include a Notice of Certification for ANDA No. 205064 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("Hetero's '760 letter") as to the '760 patent.

32. Hetero's '760 letter alleges that the established name of the drug product that is the subject of Hetero USA, Inc.'s ANDA is "aripiprazole tablets (2mg, 5mg, 10mg, 15mg, 20mg and 30mg)."

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

34. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero USA, Inc. has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to

the FDA, ANDA No. 205064 seeking approval to manufacture, use, offer to sell and sell Hetero's generic products before the expiration date of the '760 patent.

35. Upon information and belief, Hetero USA, Inc.'s actions relating to Hetero USA, Inc.'s ANDA No. 205064 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Hetero Drugs Limited, Hetero Labs Limited and Hetero USA, Inc.

THIRD COUNT FOR PATENT INFRINGEMENT

36. Otsuka realleges, and incorporates in full herein, paragraphs 16-19.

37. 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 C.

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

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

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

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

42. Otsuka received a letter from Hetero USA, Inc. dated November 24, 2014, purporting to include a Notice of Certification for ANDA No. 205064 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("Hetero's '350 letter") as to the '350 patent.

43. Hetero's '350 letter alleges that the established name of the drug product that is the subject of Hetero USA, Inc.'s ANDA is "aripiprazole tablets (2mg, 5mg, 10mg, 15mg, 20mg and 30mg)."

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

45. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero USA, Inc. has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205064 seeking approval to manufacture, use, offer to sell and sell Hetero's generic products before the expiration date of the '350 patent.

46. Upon information and belief, Hetero USA, Inc.'s actions relating to Hetero USA, Inc.'s ANDA No. 205064 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Hetero Drugs Limited, Hetero Labs Limited and Hetero USA, Inc.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Hetero Drugs Limited, Hetero Labs Limited and Hetero USA, Inc. 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), Hetero has infringed at least one claim of the '796 patent through Hetero USA, Inc.'s submission of ANDA No. 205064 to the FDA to obtain approval to manufacture, use, offer to sell and sell Hetero's generic products in the United States before the expiration of the '796 patent;

2) order that the effective date of any approval by the FDA of Hetero'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;

3) enjoin Hetero from the manufacture, use, offer for sale and sale of Hetero's generic products until the expiration of the '796 patent, or such later date as the Court may determine;

4) enjoin Hetero and all persons acting in concert with Hetero, from seeking, obtaining or maintaining approval of Hetero USA, Inc.'s ANDA No. 205064 until expiration of the '796 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed at least one claim of the '760 patent through Hetero USA, Inc.'s submission of ANDA No. 205064 to the FDA to obtain approval to manufacture, use, offer to sell and sell Hetero's generic products in the United States before the expiration of the '760 patent;

6) order that the effective date of any approval by the FDA of Hetero'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;

7) enjoin Hetero from the manufacture, use, offer for sale and sale of Hetero's generic products until the expiration of the '760 patent, or such later date as the Court may determine;

8) enjoin Hetero and all persons acting in concert with Hetero, from seeking, obtaining or maintaining approval of Hetero USA, Inc.'s ANDA No. 205064 until expiration of the '760 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed at least one claim of the '350 patent through Hetero USA, Inc.'s submission of ANDA No. 205064 to the FDA to obtain approval to manufacture, use, offer to sell and sell

Hetero's generic products in the United States before the expiration of the '350 patent;

10) order that the effective date of any approval by the FDA of Hetero's 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;

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

12) enjoin Hetero and all persons acting in concert with Hetero, from seeking, obtaining or maintaining approval of Hetero USA, Inc.'s ANDA No. 205064 until expiration of the '350 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,

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