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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. INDOCO REMEDIES LIMITED and HETERO LABS LIMITED, Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Indoco Remedies Limited ("Indoco") 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, Indoco is a corporation organized and existing under the laws of India, having its principal place of business at L-32, 33, 34 Verna Industrial Area, Verna, GOA-4-3722, India.

3. 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

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"), 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 Indoco'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, sell and offer to sell generic pharmaceutical products ("Defendants' 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 Indoco. Upon information and belief, Indoco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Indoco, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Indoco 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. According to its website,

"Indoco . . . is a fully integrated, research-oriented global pharmaceutical company with a strong presence in 80 countries including USA & UK." *See* http://www.indoco.com/newsroom-pressrelease/press-release-anda-approval-18april-2013.pdf. And upon information and belief, "Indoco has 37 ANDAs at various stages" either under its own name or filed by partners, and "Indoco's products are already available in the US market." *See id.*

7. 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 drugs products. According to its website, "Hetero is one of the largest manufacturer and supplier [sic] of Active Pharmaceutical Ingredients (API's) [sic] catering to the ever increasing requirements of the global pharmaceutical market." *See* http://www.heterodrugs.com/busin-API.shtml. 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.

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

FIRST COUNT FOR PATENT INFRINGEMENT

9. 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.

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

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

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

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

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

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

16. Upon information and belief, Indoco submitted ANDA No. 207397 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.

17. Otsuka received a letter from Indoco dated February 12, 2015, purporting to include a Notice of Certification for ANDA No. 207397 under Section 505(j)(2)(B)(i) and (ii) of the Act ("Indoco's 207397 letter") as to the '615 patent.

18. Indoco's 207397 letter alleges that the established name of the drug products that are the subject of Indoco's ANDA is "aripiprazole tablets 2, 5, 10, 15, 20 and 30 mg."

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

20. 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. 207397 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '615 patent.

21. Upon information and belief, Indoco's actions relating to Indoco's ANDA No. 207397 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Indoco and Hetero Labs Limited.

SECOND COUNT FOR PATENT INFRINGEMENT

22. Otsuka realleges, and incorporates in full herein, paragraphs 13-18.

23. 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.

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

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

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

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

28. Indoco's 207397 letter purports to include a Notice of Certification for ANDA No. 207397 under Section 505(j)(2)(B)(i) and (ii) of the Act as to the '796 patent.

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

30. 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. 207397 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '796 patent.

31. Upon information and belief, Indoco's actions relating to Indoco's ANDA No. 207397 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Indoco and Hetero Labs Limited.

THIRD COUNT FOR PATENT INFRINGEMENT

32. Otsuka realleges, and incorporates in full herein, paragraphs 13-18.

33. 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.

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

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

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

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

38. Indoco's 207397 letter purports to include a Notice of Certification for ANDA No. 207397 under Section 505(j)(2)(B)(i) and (ii) of the Act as to the '760 patent.

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

40. 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. 207397 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '760 patent.

41. Upon information and belief, Indoco's actions relating to Indoco's ANDA No. 207397 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Indoco and Hetero Labs Limited.

FOURTH COUNT FOR PATENT INFRINGEMENT

42. Otsuka realleges, and incorporates in full herein, paragraphs 13-18.

43. 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.

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

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

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

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

48. Indoco's 207397 letter purports to include a Notice of Certification for ANDA No. 207397 under Section 505(j)(2)(B)(i) and (ii) of the Act as to the '350 patent.

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

50. 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. 207397 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration of the '350 patent.

51. Upon information and belief, Indoco's actions relating to Indoco's ANDA No. 207397 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Indoco 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 Indoco's submission of ANDA No. 207397 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 Indoco's ANDA No. 207397 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 Indoco's submission of ANDA No. 207397 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 Indoco's ANDA No. 207397 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 Indoco's submission of ANDA No. 207397 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 Indoco's ANDA No. 207397 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 Indoco's submission of ANDA No. 207397 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 Indoco's ANDA No. 207397 until expiration of the '350 patent;

17) 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

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

Respectfully submitted,

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