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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ZYDUS PHARMACEUTICALS USA INC. and CADILA HEALTHCARE LIMITED, Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Zydus Pharmaceuticals USA Inc. ("Zydus USA") and Cadila Healthcare Limited (collectively, "Zydus"), 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, Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

3. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Cadila Healthcare Limited (d/b/a "Zydus Cadila"). Upon information and belief, Cadila Healthcare Limited is a corporation organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, Gujarat, 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. 8,518,421 ("the '421 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 Zydus USA's filing of two Abbreviated New Drug Applications ("ANDAs") 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, sale, offer to sell and import generic pharmaceutical products ("Zydus USA's generic products") prior to the expirations of the asserted patents.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, this Court has jurisdiction over Zydus USA. Upon information and belief, Zydus USA was incorporated in New Jersey and has its principal place of business in New Jersey. Upon information and belief, Zydus USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including

generic drug products. Upon information and belief, Zydus USA, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Zydus USA purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Zydus USA's generic products. Upon information and belief, Zydus USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil action initiated in this jurisdiction.

7. Upon information and belief, this Court additionally has jurisdiction over Zydus USA because it has availed itself of the rights and benefits of this judicial district, having stated in two purported Offers of Confidential Access, dated April 3, 2014, that "[t]his Agreement shall be governed in accordance with the laws of the state of New Jersey without regard to its conflict-of-law rules."

8. Upon information and belief, this Court has jurisdiction over Cadila Healthcare Limited. Upon information and belief, Cadila Healthcare Limited is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Cadila Healthcare Limited, directly or through its subsidiary Zydus USA, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district.

9. Upon information and belief, Zydus USA and Cadila Healthcare Limited work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

10. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

11. 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.

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

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

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

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

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

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

18. Upon information and belief, Zydus USA submitted ANDA No. 90-472 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, sale, offer to sell and import generic products containing 5, 10, 15, 20 and 30 mg of aripiprazole ("Zydus USA's tablet generic products") in the United States.

19. Otsuka received a letter from Zydus USA dated April 3, 2014, purporting to include a Notice of Certification for ANDA No. 90-472 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '615 patent. Otsuka also received a letter from Zydus USA dated April 3, 2014, purporting

to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '615 patent. Both letters are referred to collectively herein as "Zydus USA's letter."

20. Zydus USA's letter alleges that Zydus USA's tablet generic products are "Aripiprazole Oral Tablets."

21. Upon information and belief, Zydus USA's tablet generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

22. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-472 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA's tablet generic products before the expiration date of the '615 patent.

23. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-472 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

SECOND COUNT FOR PATENT INFRINGEMENT

24. Otsuka realleges, and incorporates in full herein, paragraphs 11-14.

25. Otsuka is the holder of NDA No. 21-729 for orally disintegrating tablets ("ODT") containing aripiprazole, which the FDA approved on June 7, 2006.

26. Otsuka lists the '615 patent in the Orange Book for NDA No. 21-729.

27. Otsuka markets ODT containing aripiprazole in the United States under the trademark Abilify®.

28. Upon information and belief, Zydus USA submitted ANDA No. 90-165 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use,

sale, offer to sell and import generic products containing 10, 15, 20 and 30 mg of aripiprazole ("Zydus USA's ODT generic products") in the United States.

29. Zydus USA's letter purports to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '615 patent.

30. Zydus USA's letter alleges that Zydus USA's ODT generic products are "Aripiprazole Orally Disintegrating Tablets."

31. Upon information and belief, Zydus USA's ODT generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

32. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-165 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA's ODT generic products before the expiration date of the '615 patent.

33. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-165 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

THIRD COUNT FOR PATENT INFRINGEMENT

34. Otsuka realleges, and incorporates in full herein, paragraphs 15, 17, 18 and 20.

35. 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.

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

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

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

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

40. Zydus USA's letter purports to include a Notice of Certification for ANDA No. 90-472 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '796 patent.

41. Upon information and belief, Zydus USA's tablet generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

42. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-472 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA's tablet generic products before the expiration date of the '796 patent.

43. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-472 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

FOURTH COUNT FOR PATENT INFRINGEMENT

44. Otsuka realleges, and incorporates in full herein, paragraphs 25, 27, 28, 30 and 35-38.

45. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-729.

46. Zydus USA's letter purports to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '796 patent.

47. Upon information and belief, Zydus USA's ODT generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

48. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the

FDA, ANDA No. 90-165 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA's ODT generic products before the expiration date of the '796 patent.

49. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-165 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

FIFTH COUNT FOR PATENT INFRINGEMENT

50. Otsuka realleges, and incorporates in full herein, paragraphs 15, 17 18 and 20.

51. 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.

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

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

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

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

56. Zydus USA's letter purports to include a Notice of Certification for ANDA No. 90-472 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '760 patent.

57. Upon information and belief, Zydus USA's tablet generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

58. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-472 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA's tablet generic products before the expiration date of the '760 patent.

59. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-472 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

SIXTH COUNT FOR PATENT INFRINGEMENT

60. Otsuka realleges, and incorporates in full herein, paragraphs 25, 27, 28, 30 and 51-54.

61. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-729.

62. Zydus USA's letter purports to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '760 patent.

63. Upon information and belief, Zydus USA's ODT generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

64. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-165 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA's ODT generic products before the expiration date of the '760 patent.

65. Upon information and belief, Zydus USA's actions relating to Zydus USA's ANDA No. 90-165 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

SEVENTH COUNT FOR PATENT INFRINGEMENT

66. Otsuka realleges, and incorporates in full herein, paragraphs 25, 27, 28 and 30.

67. The PTO issued the '421 patent on August 27, 2013, entitled "Flashmelt Oral Dosage Formulation." A copy of the '421 patent is attached as Exhibit D.

68. Otsuka is the owner of the '421 patent by virtue of assignment.

69. The '421 patent expires on July 24, 2021 (including pediatric exclusivity).

70. The ’421 patent is directed to and claims, *inter alia*, flashmelt pharmaceutical dosage forms.

71. Otsuka lists the ’421 patent in the Orange Book for NDA No. 21-729.

72. Zydus USA’s letter purports to include a Notice of Certification for ANDA No. 90-165 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the ’421 patent.

73. Upon information and belief, Zydus USA’s ODT generic products will, if approved and marketed, infringe at least one claim of the ’421 patent.

74. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus USA has infringed at least one claim of the ’421 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-165 seeking approval to manufacture, use, sale, offer to sell and import Zydus USA’s ODT generic products before the expiration date of the ’421 patent.

75. Upon information and belief, Zydus USA’s actions relating to Zydus USA’s ANDA No. 90-165 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Cadila Healthcare Limited.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Zydus USA and Cadila Healthcare Limited 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), Zydus has infringed at least one claim of the ’615 patent through Zydus USA’s submission of ANDA No. 90-472 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Zydus USA’s tablet 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 Zydus USA's tablet 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 Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's tablet generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-472 until the expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '615 patent through Zydus USA's submission of ANDA No. 90-165 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Zydus USA's ODT generic products in the United States before the expiration of the '615 patent;

6) order that the effective date of any approval by the FDA of Zydus USA's ODT 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;

7) enjoin Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's ODT generic products until the expiration of the '615 patent, or such later date as the Court may determine;

8) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-165 until the expiration of the '615 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '796 patent through Zydus USA's submission of ANDA No. 90-472 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Zydus USA's tablet generic products in the United States before the expiration of the '796 patent;

10) order that the effective date of any approval by the FDA of Zydus USA's tablet 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;

11) enjoin Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's tablet generic products until the expiration of the '796 patent, or such later date as the Court may determine;

12) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-472 until the expiration of the '796 patent;

13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '796 patent through Zydus USA's submission of ANDA No. 90-165 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Zydus USA's ODT generic products in the United States before the expiration of the '796 patent;

14) order that the effective date of any approval by the FDA of Zydus USA's ODT 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;

15) enjoin Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's ODT generic products until the expiration of the '796 patent, or such later date as the Court may determine;

16) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-165 until the expiration of the '796 patent;

17) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '760 patent through Zydus USA's submission of ANDA No. 90-472 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Zydus USA's tablet generic products in the United States before the expiration of the '760 patent;

18) order that the effective date of any approval by the FDA of Zydus USA's tablet 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;

19) enjoin Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's tablet generic products until the expiration of the '760 patent, or such later date as the Court may determine;

20) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-472 until the expiration of the '760 patent;

21) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '760 patent through Zydus USA's submission of ANDA No. 90-165 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import

Zydus USA's ODT generic products in the United States before the expiration of the '760 patent;

22) order that the effective date of any approval by the FDA of Zydus USA's ODT 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;

23) enjoin Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's ODT generic products until the expiration of the '760 patent, or such later date as the Court may determine;

24) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-165 until the expiration of the '760 patent;

25) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '421 patent through Zydus USA's submission of ANDA No. 90-165 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Zydus USA's ODT generic products in the United States before the expiration of the '421 patent;

26) order that the effective date of any approval by the FDA of Zydus USA's ODT generic products be a date that is not earlier than the expiration of the '421 patent, or such later date as the Court may determine;

27) enjoin Zydus from the manufacture, use, sale, offer to sell and import of Zydus USA's ODT generic products until the expiration of the '421 patent, or such later date as the Court may determine;

28) enjoin Zydus and all persons acting in concert with Zydus, from seeking, obtaining or maintaining approval of Zydus USA's ANDA No. 90-165 until the expiration of the '421 patent;

29) 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

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

Respectfully submitted,

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Dated: May 16, 2014

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