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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., PRINSTON PHARMACEUTICAL INC. and SOLCO HEALTHCARE U.S., LLC, Defendants.	Civil Action No.: 14-cv-5537-JBS-KMW

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai"), Huahai US Inc. ("Huahai US"), Prinston Pharmaceutical Inc. ("Prinston") and Solco Healthcare U.S., LLC ("Solco") (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, Zhejiang Huahai is a corporation organized and existing under the laws of the People's Republic of China, having its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

3. Upon information and belief, Huahai US is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512. Upon information and belief, Zhejiang Huahai is the parent company of Huahai US.

4. Upon information and belief, Prinston is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512. Upon information and belief, Zhejiang Huahai is the parent company of Prinston.

5. Upon information and belief, Solco is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512. Upon information and belief, Solco is a wholly-owned subsidiary of Prinston.

NATURE OF THE ACTION

6. 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 Prinston'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, offer to sell and import generic pharmaceutical products ("Prinston's generic products") prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This court has jurisdiction over Zhejiang Huahai. Upon information and belief, Zhejiang Huahai is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Zhejiang Huahai, directly or through its wholly-owned subsidiaries, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Zhejiang Huahai manufactures "fomulations [sic], APIs . . . and intermediates" and was "the first pharmaceutical company in China that . . . passed USA FDA approval." *See* http://en.huahaipharm.com/content.asp?info_kind=001002. Upon information and belief, Zhejiang Huahai's website states that "[w]ith a total asset of 1,900 million yuan, the company has 11branches [sic] (subsidiaries) in the United States, Shanghai, Hangzhou, and Linhai." *Id*. Upon information and belief, Zhejiang Huahai's website also states that "[a]ll products of Huahai Pharmaceuticals have passed the national GMP approval, most of which have also been officially certified on the international mainstream markets of the United States, Australia, Korea, European Union and so on, having established its status as one of the pharmaceutical enterprises that have obtained the most international approval in the field." *See*

http://en.huahaipharm.com/Certificate.asp?info_kind=008003. Upon information and belief, Zhejiang Huahai owns subsidiaries, Huahai US, Prinston and Solco, all of which share a common address at 2002 Eastpark Blvd., Cranbury, NJ 08512. Upon information and belief, Zhejiang Huahai's subsidiary Huahai US reports that it assisted its parent company, Zhejiang Huahai, "to become the first Chinese pharmaceutical company awarded with a contract manufacturing project for a well-known brand name pharmaceutical company for an under-patent product." *See* http://huahaius.com/history.html.

9. This court has jurisdiction over Huahai US. Upon information and belief, Huahai US is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Huahai US, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Huahai US's website indicates that it is "the most important subsidiary component of Zhejiang Huahai" and is "engaged in marketing and sales for the North American market[.]" *See* http://huahaius.com/about%20us.html. Upon information and belief, Huahai US's website states that "[c]urrently, Huahai US Inc has 35 US DMFs and assisted Prinston Pharmaceutical Inc. to get over 15 ANDAs approved by FDA." *See* http://huahaius.com/history.html. Upon information and belief, Huahai US's website also states that "[i]n 2010, the company began to market generic finished dosage products through the subsidiary company, Prinston Pharmaceutical Inc[.]" *Id*. Upon information and belief, Huahai US shares common corporate officers with Prinston.

10. This Court has jurisdiction over Prinston. Upon information and belief, Prinston is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Prinston, directly or

indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Prinston purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Prinston's generic products. Upon information and belief, Prinston is registered as a wholesaler in the State of New Jersey (No. 5004252) under the trade name "Solco Healthcare US LLC." *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx.

11. Upon information and belief, this Court additionally has jurisdiction over Prinston because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated July 21, 2014, that "[t]his Agreement shall be governed by the laws of the State of New Jersey" and that it "irrevocably submit[s] to and accept[s], generally and unconditionally, the exclusive personal jurisdiction of the courts of the State of New Jersey and waives its right to assert any objection or defense based on venue or *forum non conveniens* and agrees to be bound by any judgment rendered thereby arising under or in respect of this Agreement."

12. This Court has jurisdiction over Solco. Upon information and belief, Solco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Solco, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Prinston's website states: "Solco Healthcare U.S. is the U.S. sales and marketing division of Prinston Pharmaceutical Inc." and "provides state-of-the-art, FDA-approved manufacturing capabilities and a U.S. management team experienced in

manufacturing and launching generic and branded pharmaceuticals, as well as OTC products." *See* http://www.prinstonpharm.com/Subsidiary.html.

13. Upon information and belief, Zhejiang Huahai, Huahai US, Prinston and Solco 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, Zhejiang Huahai's subsidiary Huahai US reports that it assisted its parent company, Zhejiang Huahai, "to become the first Chinese pharmaceutical company awarded with a contract manufacturing project for a well-known brand name pharmaceutical company for an under-patent product." *See* http://huahaius.com/history.html. Upon information and belief, Huahai US's website states that it "assisted Prinston Pharmaceutical Inc. to get over 15 ANDAs approved by [the] FDA." *See* http://huahaius.com/history.html. Upon information and belief, Huahai US's website also states that "[i]n 2010, the company began to market generic finished dosage products through the subsidiary company, Prinston Pharmaceutical Inc[.]" *Id*. Upon information and belief, Prinston's website indicates that it is "a fully integrated generic company specialized in . . . CNS and anti-depressant drugs." *See* http://www.prinstonpharm.com/News.html. Upon information and belief, Prinston's website markets to the United States numerous generic products identifying Solco as the product distributer and Zhejiang Huahai as the product manufacturer. *See* http://www.prinstonpharm.com/Products_List.html.

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

FIRST COUNT FOR PATENT INFRINGEMENT

15. 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.

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

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

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

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

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

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

22. Upon information and belief, Prinston submitted ANDA No. 20-5363 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 Prinston's generic products in the United States.

23. Otsuka received a letter from Prinston dated July 21, 2014, purporting to include a Notice of Certification for ANDA No. 20-5363 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) ("Prinston's 20-5363 letter") as to the '615 patent.

24. Prinston's 20-5363 letter alleges that the name of the drug product that is subject of the Prinston ANDA is aripiprazole tablets.

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

26. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Prinston has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-5363 seeking approval to manufacture, use, import, offer to sell and sell Prinston's generic products before the expiration date of the '615 patent.

27. Upon information and belief, Prinston's actions relating to Prinston's ANDA No. 20-5363 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Zhejiang Huahai, Huahai US, Prinston and Solco.

SECOND COUNT FOR PATENT INFRINGEMENT

28. Otsuka realleges, and incorporates in full herein, paragraphs 19–24.

29. 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.

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

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

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

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

34. Prinston's 20-5363 letter purports to include a Notice of Certification for ANDA No. 20-5363 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '796 patent.

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

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

FDA, ANDA No. 20-5363 seeking approval to manufacture, use, import, offer to sell and sell Prinston's generic products before the expiration date of the '796 patent.

37. Upon information and belief, Prinston's actions relating to Prinston's ANDA No. 20-5363 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Zhejiang Huahai, Huahai US, Prinston and Solco.

THIRD COUNT FOR PATENT INFRINGEMENT

38. Otsuka realleges, and incorporates in full herein, paragraphs 19–24.

39. 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.

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

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

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

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

44. Prinston's 20-5363 letter purports to include a Notice of Certification for ANDA No. 20-5363 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '760 patent.

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

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

FDA, ANDA No. 20-5363 seeking approval to manufacture, use, import, offer to sell and sell Prinston's generic products before the expiration date of the '760 patent.

47. Upon information and belief, Prinston's actions relating to Prinston's ANDA No. 20-5363 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Zhejiang Huahai, Huahai US, Prinston and Solco.

FOURTH COUNT FOR PATENT INFRINGEMENT

48. Otsuka realleges, and incorporates in full herein, paragraphs 19–24.

49. 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.

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

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

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

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

54. Upon information and belief, Defendants have actual knowledge of the '350 patent.

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

56. Upon information and belief, the label for Prinston's generic products will recommend, suggest, encourage and/or instruct others to use Prinston's generic products in a manner that infringes at least one claim of the '350 patent

57. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Prinston has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-5363 seeking approval to manufacture, use, import, offer to sell and sell Prinston's generic products before the expiration date of the '350 patent.

58. Upon information and belief, Prinston's actions relating to Prinston's ANDA No. 20-5363 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Zhejiang Huahai, Huahai US, Prinston and Solco.

FIFTH COUNT FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

59. Otsuka realleges, and incorporates in full herein, paragraphs 19-24 and 49-57.

60. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. 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.

62. Defendants have made, and continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Prinston's generic products prior to expiration of the '350 patent.

63. Defendants' actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 20-5363 seeking approval to manufacture, use, import, offer to sell and sell Prinston's 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.

64. Upon information and belief, the FDA may approve ANDA No. 20-5363 as early as the April 20, 2015, expiration of the Pediatric Exclusivity period associated with U.S. Patent No. 5,006,528.

65. Upon information and belief, Defendants intend to manufacture, use, offer for sale, sell and/or import Prinston's generic products upon FDA approval of ANDA No. 20-5363.

66. Any commercial manufacture, use, offer for sale, sale and/or importation of Prinston's 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).

67. Otsuka will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

68. Otsuka does not have an adequate remedy at law.

69. Otsuka is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Prinston's generic products prior to expiration of the '350 patent by Defendants 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 Prinston's submission of ANDA No. 20-5363 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Prinston's 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 Prinston's 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 Prinston's 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 Prinston's ANDA No. 20-5363 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 Prinston's submission of ANDA No. 20-5363 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Prinston's 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 Prinston'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;

7) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Prinston's 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 Prinston's ANDA No. 20-5363 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 Prinston's submission of ANDA No. 20-5363 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Prinston's 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 Prinston'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;

11) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Prinston's 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 Prinston's ANDA No. 20-5363 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 Prinston's submission of ANDA No. 20-5363 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Prinston's 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 Prinston'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;

15) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Prinston's 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 Prinston's ANDA No. 20-5363 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 Prinston's generic products prior to expiration of the '350 patent by Defendants 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 Prinston's 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.

Dated: April 7, 2015

Respectfully submitted,

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