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.:

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. 9,359,302 ("the '302 patent") and U.S. Patent No. 9,387,182 ("the '182 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 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, import, sell and offer to sell generic pharmaceutical products ("Defendants' 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 and 1338(a).

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 (accessed November 1, 2016). 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 (accessed November 1, 2016). 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 (accessed November 1, 2016).

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 (accessed November 1, 2016). 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 (accessed November 1, 2016). 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 Defendants' 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 (accessed November 1, 2016).

11. 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 (accessed November 1, 2016).

12. 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 (accessed November 1, 2016). 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 (accessed November 1, 2016). 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/archived%20news.html (accessed November 1, 2016).

13. Upon information and belief, Prinston's website markets to the United States numerous generic products identifying Solco as the product distributer. *See* http://www.prinstonpharm.com/Products_List.html (accessed November 1, 2016).

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 '302 patent on June 7, 2016, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '302 patent is attached as Exhibit A.

16. Otsuka is the owner of the '302 patent by virtue of assignment.

17. The '302 patent expires on September 25, 2022, excluding any pediatric exclusivity.

18. The '302 patent is directed to and claims, *inter alia,* aripiprazole crystals, pharmaceutical compositions and methods of treatment.

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 '302 and '182 patents 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 Defendants' generic products in the United States.

23. Otsuka received a letter from Prinston dated September 22, 2016 ("Prinston's letter"), purporting to include a Notice of Certification for ANDA No. 20-5363 under 21 U.S.C. § 355(j)(2)(B)(i) and (ii) as to the '302 and '182 patents.

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

25. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '302 patent.

26. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '302 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 Defendants' generic products before the expiration date of the '302 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 '182 patent on July 12, 2016, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '182 patent is attached as Exhibit B.

30. Otsuka is the owner of the '182 patent by virtue of assignment.

31. The '182 patent expires on December 25, 2023, excluding any pediatric exclusivity.

32. The '182 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment.

33. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '182 patent.

34. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '182 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 Defendants' generic products before the expiration date of the '182 patent.

35. 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.

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 '302 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 Defendants' generic products in the United States before the expiration of the '302 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 '302 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 '302 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 '302 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '182 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 Defendants' generic products in the United States before the expiration of the '182 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 '182 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 '182 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 '182 patent;

9) 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

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

Respectfully submitted,

s/ Melissa Chuderewicz
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Dated: November 4, 2016

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