UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. STANDARD CHEM. & PHARM. CO., LTD., STASON PHARMACEUTICALS INC., ZHEJIANG JINHUA CONBA BIO-PHARM CO., LTD., TAI HENG INDUSTRY CO., LTD. and BRECKENRIDGE PHARMACEUTICAL, INC., Defendants.	Civil Action No.: 15-cv-6353-JBS-KMW

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Standard Chem. & Pharm. Co., Ltd. ("Standard"), Stason Pharmaceuticals Inc., (collectively, "Stason") Zhejiang Jinhua Conba Bio-Pharm Co., Ltd. ("Zhejiang Jinhua"), Tai Heng Industry Co., Ltd. ("Tai Heng") and Breckenridge Pharmaceutical, Inc. ("Breckenridge") (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, Standard is a corporation organized and existing under the laws of Taiwan with its corporate headquarters at No. 6-20, Tuku, Tuku Village, Sinying District, Tainan City 73055, Taiwan.

3. Upon information and belief, Stason Pharmaceuticals Inc. is a private corporation organized and existing under the laws of the State of California, having its headquarters and principal place of business at 11 Morgan, Irvine, CA 92618. Upon information and belief, Standard is the parent company of Stason Pharmaceuticals Inc.

4. Upon information and belief, Zhejiang Jinhua is a corporation organized and existing under the laws of the People's Republic of China, having its principal place of business at 288 Jinqu Road, Jinhua, Zhejiang 321016, People's Republic of China.

5. Upon information and belief, Tai Heng is a corporation organized and existing under the laws of the People's Republic of China, having its principal place of business at 4F Block A2, Shanghai Industrial Investment Building, No. 18 Cao Xi Road (North), Shanghai, People's Republic of China.

6. Upon information and belief, Breckenridge is a private corporation organized and existing under the laws of the State of Florida, having a place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, FL 33487.

NATURE OF THE ACTION

7. 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 Stason'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, offer to sell and sell generic

pharmaceutical products ("Defendants' generic products") prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

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

9. This Court has jurisdiction over Standard. Upon information and belief, Standard is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Standard, 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, Standard "dedicate[s] [itself] to . . . manufacturing, and market expansion" and "plays an important role in [the] global supply chain." *See* www.standard.com.tw. Upon information and belief, Standard has "developed ANDA business in [the] United States for years," "focuses on generic pharmaceuticals" and "works with research institutes, government agencies, academic research, etc. for commercializing [its] research and/or development." *See* www.standard.com.tw. Upon information and belief, Standard has submitted Drug Master Files ("DMF") to the U.S. Food and Drug Administration ("FDA") and "sold [API] to . . . overseas pharmaceuticals companies." *See* www.standard.com.tw.

10. This Court has jurisdiction over Stason Pharmaceuticals Inc. Upon information and belief, Stason Pharmaceuticals Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Stason Pharmaceuticals Inc. directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Stason Pharmaceuticals 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 Defendants'

generic products. Upon information and belief, Stason Pharmaceuticals Inc. "engages in the development, manufacture, importation/exportation, licensing, and marketing of generic . . . drug products in the United States." *See* http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId= 3610047. Upon information and belief, Stason "entered the US generic market in 1994," "currently holds a portfolio of approved ANDAs" and is "geared to file 4-5 or more ANDAs per year in the areas of oncology and CNS." *See* http://www.stasonpharma.com/divisions/generic/.

11. Upon information and belief, Standard and Stason Pharmaceuticals Inc. 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, Stason is "vertically integrated, from process development of the API to the submission of dossiers for finished products." *See* http://www.stasonpharma.com/divisions/generic/.

12. This Court has jurisdiction over Zhejiang Jinhua. Upon information and belief, Zhejiang Jinhua is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Zhejiang Jinhua, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Zhejiang Jinhua is a supplier of aripiprazole drug substance. *See* http://en.jhconba.com/products_detail/&productId=c0cfceb3-cf42-4faa-80bd-c39fe329d57a.html.

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

manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. The Tai Heng website states that it "has more than 15 DMFs . . . active with the US FDA . . . ." *See* http://www.taihengco.com/pages/maine.htm. Furthermore, upon information and belief, Tai Heng is a supplier of aripiprazole drug substance. *See* www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/UCM370723.txt.

14. This Court has jurisdiction over Breckenridge. Upon information and belief, Breckenridge is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Breckenridge, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Breckenridge's website states that it "offers . . . Sales Marketing and Distribution to all Classes of Trade in all 50 States and PR," "ha[s] an aggressive pipeline to assure a steady stream of new products to bring to market" and "plan[s] to file more than 12 ANDAs and launch over 12 Products on an annual basis." *See* http://www.bpirx.com/html/index.aspx?p32sda=businessdevelopment&psdge87d=295&tl97abi=16. Upon information and belief, Breckenridge is registered as a wholesaler in the State of New Jersey (No. 5002974) under the trade name "Breckenridge, Inc." *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Upon information and belief, Breckenridge maintains a sales and marketing office at 1 Passaic Avenue, Fairfield, NJ 07004. Breckenridge 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.

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

FIRST COUNT FOR PATENT INFRINGEMENT

16. 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.

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

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

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

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

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

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

23. Upon information and belief, Stason Pharmaceuticals Inc. submitted ANDA No. 091279 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.

24. Otsuka received a letter from Breckenridge and Stason Pharmaceuticals Inc. dated July 9, 2015, purporting to include a Notice of Certification for ANDA No. 091279 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) ("Defendants' 091279 letter") as to the '615 patent.

25. Defendants' 091279 letter alleges that the name of the drug product that is the subject of ANDA No. 091279 is "aripiprazole tablets, oral."

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

27. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Stason Pharmaceuticals Inc. has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 091279 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '615 patent.

28. Upon information and belief, Stason Pharmaceuticals Inc.'s actions relating to Stason Pharmaceuticals Inc.'s ANDA No. 091279 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Standard, Breckenridge, Zhejiang Jinhua, Tai Heng and Stason Pharmaceuticals Inc.

SECOND COUNT FOR PATENT INFRINGEMENT

29. Otsuka realleges, and incorporates in full herein, paragraphs 20-25.

30. 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.

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

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

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

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

35. Defendants' 091279 letter purports to include a Notice of Certification for ANDA No. 091279 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '796 patent.

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

37. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Stason Pharmaceuticals Inc. has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 091279 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '796 patent.

38. Upon information and belief, Stason Pharmaceuticals Inc.'s actions relating to Stason Pharmaceuticals Inc.'s ANDA No. 091279 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Standard, Breckenridge, Zhejiang Jinhua, Tai Heng and Stason Pharmaceuticals Inc.

THIRD COUNT FOR PATENT INFRINGEMENT

39. Otsuka realleges, and incorporates in full herein, paragraphs 20-25.

40. 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.

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

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

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

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

45. Defendants' 091279 letter purports to include a Notice of Certification for ANDA No. 091279 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '760 patent.

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

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

the FDA, ANDA No. 091279 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '760 patent.

48. Upon information and belief, Stason Pharmaceuticals Inc.'s actions relating to Stason Pharmaceuticals Inc.'s ANDA No. 091279 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Standard, Breckenridge, Zhejiang Jinhua, Tai Heng and Stason Pharmaceuticals Inc.

FOURTH COUNT FOR PATENT INFRINGEMENT

49. Otsuka realleges, and incorporates in full herein, paragraphs 20-25.

50. 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.

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

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

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

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

55. Defendants have actual knowledge of the '350 patent.

56. Defendants' 091279 letter purports to include a Notice of Certification for ANDA No. 091279 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '350 patent.

57. Upon information and belief, if approved and marketed, physicians, pharmacists and/or patients will directly infringe the '350 patent by the sale and use of Defendants' generic products in accordance with the claims of the '350 patent..

58. Upon information and belief, Defendants have taken active steps to intentionally induce infringement of the ’350 patent.

59. Upon information and belief, Defendants have taken active steps to encourage the sale and use of Defendants’ generics products by physicians, pharmacists and/or patients in accordance with the claims of the ’350 patent by providing information and instructions in the tablet package insert for Defendants’ generic products encouraging the sale and use of aripiprazole in accordance with the claims of the ’350 patent.

60. Upon information and belief, Defendants have taken active steps to encourage the sale and use of Defendants’ generic products by physicians, pharmacists and/or patients in accordance with the claims of the ’350 patent by using marketing materials to actively encourage the sale and use of Defendants’ generic products as a substitute for Abilify® for all purposes, including those in accordance with the claims of the ’350 patent.

61. 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. 091279 seeking approval to manufacture, use, import, offer to sell and sell Defendants’ generic products before the expiration date of the ’350 patent, and by taking active steps to encourage the sale and use of Defendants’ generic products in accordance with the claims of the ’350 patent by physicians, pharmacists and/or patients with the specific intent to encourage such infringement.

62. Upon information and belief, Stason Pharmaceuticals Inc.’s actions relating to Stason Pharmaceuticals Inc.’s ANDA No. 091279 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Standard, Breckenridge, Zhejiang Jinhua, Tai Heng and Stason Pharmaceuticals Inc.

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 Stason Pharmaceuticals Inc.'s submission of ANDA No. 091279 to the FDA to obtain approval to manufacture, use, 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 Stason Pharmaceuticals Inc.'s ANDA No. 091279 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 Stason Pharmaceuticals Inc.'s submission of ANDA No. 091279 to the FDA to obtain approval to manufacture, use, 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 Stason Pharmaceuticals Inc.'s ANDA No. 091279 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 Stason Pharmaceuticals Inc.'s submission of ANDA No. 091279 to the FDA to obtain approval to manufacture, use, 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 Stason Pharmaceuticals Inc.'s ANDA No. 091279 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 Stason Pharmaceuticals Inc.'s submission of ANDA No. 091279 to the FDA to obtain approval to manufacture, use, 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 Stason Pharmaceuticals Inc.'s ANDA No. 091279 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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