

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

V.

Civil Action No.:

STASON INDUSTRIAL CORP., STASON
PHARMACEUTICALS INC., ZHEJIANG
JINHUA CONBA BIO-PHARM CO., LTD.,
TAI HENG INDUSTRY CO., LTD. and
BRECKENRIDGE PHARMACEUTICAL,
INC.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Stason Industrial Corp. (“Stason Industrial”), 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, Stason Industrial is a 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.

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, Stason Industrial 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. 9,359,302 ("the '302 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 Pharmaceuticals Inc.'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 patent.

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 Stason Industrial. Upon information and belief, Stason Industrial is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Stason Industrial, directly or through its wholly-owned subsidiaries including Stason Pharmaceuticals Inc., manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district.

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> (accessed October 10, 2016). 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/> (accessed October 10, 2016).

11. Upon information and belief, Stason Industrial 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/> (accessed October 10, 2016). Upon information and belief, Stason Industrial and Stason Pharmaceuticals Inc. share a common corporate officer.

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 (accessed October 10, 2016).

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/main.htm> (accessed October 10, 2016). 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 (accessed October 10, 2016).

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" and "ha[s] an aggressive pipeline to assure a steady stream of new products to bring to market." *See* <http://www.bpirx.com/html/index.aspx?p32sda=businessdevelopment&psdge87d=295&tl97abi=16> (accessed October 10, 2016). 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> (accessed October 10, 2016). 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 § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

16. 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.

17. Otsuka is the owner of the ’302 patent by virtue of assignment.

18. The ’302 patent expires on September 25, 2022, excluding any pediatric exclusivity.

19. The ’302 patent is directed to and claims, inter alia, aripiprazole crystals, pharmaceutical compositions and methods of treatment.

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 ’302 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 August 30, 2016, purporting to include a Notice of Certification for ANDA No. 091279 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (“Defendants’ letter”) as to the ’302 patent.

25. Defendants’ 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, the manufacture, use, import, offer for sale and sale of Defendants’ generic products will, if approved and marketed, directly infringe at least one claim of the ’302 patent.

27. 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. 091279 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '302 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 Stason Industrial, 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 '302 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 '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 Stason Pharmaceuticals Inc.'s ANDA No. 091279 until expiration of the '302 patent;
- 5) 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
- 6) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

s/ Melissa A. Chuderewicz
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