

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____)	
OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
SUN PHARMACEUTICAL INDUSTRIES)	
LTD., SUN PHARMA GLOBAL INC., SUN)	
PHARMA GLOBAL FZE, SUN PHARMA)	
USA, SUN PHARMACEUTICALS)	
INDUSTRIES, INC. and CARACO)	
PHARMACEUTICAL LABORATORIES,)	
LTD.,)	
Defendants.)	
_____)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Sun Pharmaceutical Industries Ltd. (“Sun Ltd.”), Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharma USA (“Sun USA”), Sun Pharmaceuticals Industries, Inc. and Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) (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, Sun Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, 400 059, India.

3. Upon information and belief, Sun Pharma Global Inc. is a corporation organized and existing under the laws of the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Upon information and belief, Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Ltd.

4. Upon information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), Sharjah, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Global Inc.

5. Upon information and belief, Sun USA is a wholly-owned subsidiary of Sun Ltd., with its principal place of business at 1150 Elijah McCoy Drive, Detroit, MI, 48202.

6. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is a corporation organized and existing under the laws of Michigan, having a facility at 270 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is a wholly-owned subsidiary of Sun Ltd. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is the U.S. entity of Sun Ltd. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is an authorized agent of Sun Pharma Global FZE.

7. Upon information and belief, Caraco is a corporation organized and existing under the laws of Michigan, having a facility at 270 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Caraco is a wholly-owned subsidiary of Sun Ltd. Upon information and belief, Caraco is an authorized agent of Sun Pharma Global FZE. Upon information and belief, Caraco may also be doing business as Sun Pharmaceutical Industries, Inc.

NATURE OF THE ACTION

8. This is an action for infringement of 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 Sun Pharma Global FZE’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 and offer to sell generic pharmaceutical products (“Sun Pharma Global FZE’s generic products”) before the expiration of the asserted patent.

JURISDICTION AND VENUE

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

10. Upon information and belief, this Court has jurisdiction over Sun Ltd. Sun Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Ltd., directly or through its wholly-owned subsidiaries, including Sun Pharma Global Inc., Sun Pharma Global FZE, Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Ltd. 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.

11. Upon information and belief, this Court has jurisdiction over Sun Pharma Global Inc. Upon information and belief, Sun Pharma Global Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global Inc., directly or through its parent, subsidiaries,

affiliates and/or agents, including Sun Ltd., Sun Pharma Global FZE, Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Pharma Global Inc. 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.

12. Upon information and belief, this Court has jurisdiction over Sun Pharma Global FZE. Sun Pharma Global FZE is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global FZE, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sun Pharma Global FZE purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, in this judicial district and this judicial district is a likely destination of Sun Pharma Global FZE's generic products. Sun Pharma Global FZE's authorized agent in this judicial district is John L. Dauer Jr., Esq., Chief Patent Counsel, Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512. Additionally, Sun Pharma Global FZE has availed itself of the laws of New Jersey by, at least, indicating that an offer to access confidential information relating to Sun Pharma Global FZE's ANDA No. 78-614 "shall be governed by the laws of the State of New Jersey." Upon information and belief, Sun Pharma Global FZE 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.

13. Upon information and belief, this Court has jurisdiction over Sun USA. Sun USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun USA, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco's website states:

Sun Pharma USA is the US arm of Sun Pharmaceutical Industries, Ltd. ("Sun Pharma"), a leading pharmaceutical company in India. Sun Pharma USA consists of Sun Pharma subsidiaries Caraco Pharmaceutical Laboratories, Ltd. with locations in the Detroit, MI area, New Jersey and Ohio

See <http://www.caraco.com/asp/CorporateProfile.aspx> (emphasis added) (accessed June 4, 2014).

14. Upon information and belief, this Court has jurisdiction over Sun Pharmaceuticals Industries, Inc. Sun Pharmaceuticals Industries, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharmaceutical Industries, Inc., directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, Sun USA and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco's website states that Sun Pharmaceuticals Industries, Inc. "markets and distributes generic pharmaceuticals to the nation's largest wholesalers" and that it "is a vertically integrated manufacturer with the flexibility to develop and manufacture both in the U.S. and overseas." *See* <http://www.caraco.com/asp/CorporateProfile.aspx> (accessed Sept. 29, 2014). In addition, Sun

Pharmaceuticals Industries, Inc. maintains “a focus on creating value with quality generic pharmaceuticals with strategic focus on the needs of U.S. health care system.” *Id.* Sun Pharmaceuticals Industries, Inc. is an authorized agent for Sun Pharma Global FZE in connection with ANDA No. 78-614. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is registered in the State of New Jersey as a drug manufacturer and wholesaler, with Registration No. 5003437. Upon information and belief, Sun Pharmaceuticals Industries Inc. 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. Upon information and belief, this Court has jurisdiction over Caraco. Caraco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Caraco, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global, Inc., Sun Pharma Global FZE, Sun USA and Sun Pharmaceuticals Industries, Inc., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco is an authorized agent for Sun Pharma Global FZE in connection with ANDA No. 78-614. Upon information and belief, Caraco 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.

16. Upon information and belief, the Defendants hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

17. Upon information and belief, the Defendants 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.

18. 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

19. The U.S. Patent and Trademark Office (“PTO”) issued the ’350 patent on June 24, 2014, entitled “Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders.” A copy of the ’350 patent is attached as Exhibit A.

20. Otsuka is the owner of the ’350 patent by virtue of assignment.

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

22. The ’350 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment.

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

24. Otsuka lists the ’350 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

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

26. Upon information and belief, Sun Pharma Global FZE submitted ANDA No. 78-614 to the FDA, under Section 505(j), seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE’s generic products in the United States.

27. Otsuka received a letter from an authorized agent for Sun Pharma Global FZE, Sun Pharmaceuticals Industries, Inc., dated August 22, 2014, (“Sun Pharma Global FZE’s Letter”) purporting to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the ’350 patent.

28. Sun Pharma Global FZE’s Letter states that “the established name of the proposed drug product that is the subject of the SUN ANDA is Aripiprazole Tablets.”

29. Upon information and belief, Sun Pharma Global FZE’s generic products will, if approved and marketed, infringe at least one claim of the ’350 patent.

30. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the ’350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE’s generic products before the expiration date of the ’350 patent.

31. Upon information and belief, Sun Pharma Global FZE’s actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants on the patent infringement claim set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), the Defendants have infringed at least one claim of the ’350 patent through Sun Pharma Global FZE’s submission of ANDA No. 78-614 to the FDA to obtain approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE’s generic products in the United States before the expiration of the ’350 patent;

- 2) order that the effective date of any approval by the FDA of Sun Pharma Global FZE'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;
- 3) enjoin the Defendants from the manufacture, use, sale, offer to sell and import of Sun Pharma Global FZE's generic products until the expiration of the '350 patent, or such later date as the Court may determine;
- 4) enjoin the Defendants and all persons acting in concert with the Defendants from seeking, obtaining or maintaining approval of ANDA No. 78-614 until the expiration of the '350 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,

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