IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEIJIN LIMITED, TEIJIN PHARMA LIMITED, and TAKEDA PHARMACEUTICALS U.S.A., INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMA GLOBAL FZE and CARACO PHARMACEUTICAL LABORATORIES, LTD.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Teijin Limited ("Teijin Ltd."), together with its subsidiary Teijin Pharma Limited ("Teijin Pharma Ltd.") (collectively, "Teijin"), and Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") (collectively, "Plaintiffs"), for their Complaint against Defendants Sun Pharma Global FZE ("Sun FZE") and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") (collectively, "Sun"), hereby allege as follows:

PARTIES

1. Plaintiff Teijin Ltd. is a Japanese corporation, having a principal place of business at 6-7, Minami-Hommachi 1-chome, Chuo-ku, Osaka 541-8587, Japan.

2. Plaintiff Teijin Pharma Ltd. is a Japanese corporation, having its principal place of business at 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585, Japan.

3. Plaintiff Takeda is a Delaware corporation, having its principal place of business at 1 Takeda Parkway, Deerfield, Illinois 60015.

4. Upon information and belief, Defendant Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of

business at Executive Suite #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Aarab Emirates. Upon information and belief, Sun FZE, itself and through its agent Caraco, sells various drug products in the United States, including in this judicial district.

5. Defendant Caraco is a Michigan corporation, having a place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. Upon information and belief, Sun Pharmaceutical Industries, Inc. merged into Caraco on or about February 28, 2013, with Caraco as the surviving corporation. Upon information and belief, the merger occurred after Sun submitted ANDA No. 205467 ("Sun's ANDA").

6. Upon information and belief, Sun Pharmaceutical Industries, Inc. was a Michigan corporation, having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512. Upon information and belief, Sun Pharmaceuticals, Inc. sold and Caraco sells various drug products in the United States, including in this judicial district.

NATURE OF THE ACTION

7. This is a civil action for infringement of United States Patent No. 6,225,474 ("the '474 patent" or "the patent-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Sun FZE and Caraco by virtue of, *inter alia*, the fact that they have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Takeda Pharmaceuticals U.S.A. Inc., a

Delaware corporation. This Court has personal jurisdiction over Sun for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

10. This Court has personal jurisdiction over Sun FZE because it has previously been sued in this district and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Aventis Pharma S.A., et al. v. Sun Pharmaceutical Industries,* 09-cv-00630; *Abbott Laboratories, et al. v. Sun Pharmaceuticals Industries Ltd, et al.,* 10-cv-00112; and *Sanofi-Aventis, et al. v. Sun Pharmaceutical Industries, Ltd. et al.*, 08-cv-00350.

11. This Court has personal jurisdiction over Caraco because of its merger with Sun Pharmaceutical Industries, Inc. Sun Pharmaceutical Industries, Inc. has previously been sued in this district and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *UCB Inc. et al v Sun Pharma Global FZE et al.*, 13-cv-01218 and *Pfizer Inc. et al v. Sun Pharma Global Inc. et al.*, 09-cv-00313.

12. Upon information and belief, Caraco has not denied personal jurisdiction in this district in at least one instance. *See, e.g.*, *AstraZeneca Pharmaceuticals LP et al v. Sun Pharmaceutical Industries Ltd. et al.*, 07-cv-00806, D.I. 17 at ¶ 21.

13. This Court also has personal jurisdiction over both Sun FZE and Caraco by virtue of, *inter alia*, the fact that they have availed themselves of the rights and benefits of Delaware law, and have engaged in substantial and continuing contacts with the State.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

15. On May 1, 2001, the '474 patent, titled "Polymorphs of 2-(3-cyano-4-isobutyloxyphenyl)-4-methyl-5-thiazolecarboxylic acid and method of producing the same," was issued. A copy of the '474 patent is attached as Exhibit A. Teijin Ltd. is the owner of the '474 patent. Teijin Pharma Ltd. and Takeda hold exclusive licenses with respect to the '474 patent.

ACTS GIVING RISE TO THIS ACTION

16. Takeda holds New Drug Application ("NDA") No. 21-856 for oral tablets containing 40 or 80 mg of the active ingredient febuxostat. Takeda markets and sells these tablets in the United States under the brand name "Uloric®."

17. Pursuant to 21 U.S.C. § 355(b)(1), the '474 patent is listed in the FDA's publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering Uloric® or its use.

18. Upon information and belief, Sun submitted ANDA No. 205467 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Sun's ANDA No. 205467 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 40 and 80 mg of febuxostat ("the Sun Generic Product") prior to the expiration of the '474 patent.

19. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Sun certified in ANDA No. 205467 that the claims of the '474 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Sun Generic Product.

20. Plaintiffs received written notification of Sun's ANDA No. 205467 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated September 25, 2013 ("Notice Letter").

21. Sun's Notice Letter does not deny infringement of claims 5-6 and 8-10 of the '474 patent separate and apart from asserting invalidity.

22. Sun's Notice Letter does not refer to a certification with respect to U.S. Patent No. 5,614,520 ("the '520 patent"), and does not provide any detailed statement with regard to the '520 patent. Accordingly, upon information and belief, Sun's ANDA No. 205467 contains a "Paragraph III" certification with respect to the '520 patent pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(III). The expiration date of the '520 patent is March 25, 2019.

INFRINGEMENT BY SUN OF U.S. PATENT NO. 6,225,474

23. Plaintiffs re-allege paragraphs 1-22 as if fully set forth herein.

24. Upon information and belief, Sun's submission of ANDA No. 205467 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '474 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Sun Generic Product, if approved by the FDA, prior to the expiration of the '474 patent, including any applicable exclusivities or extensions, would infringe the '474 patent under 35 U.S.C. § 271.

26. Upon information and belief, Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sun's ANDA No. 205467 be a date that is not earlier than the expiration of the patent term

including any extension granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '474 patent to which Plaintiffs are or become entitled.

27. Plaintiffs will be irreparably harmed by Sun's infringing activities, unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

28. Upon information and belief, Sun was aware of the existence of the '474 patent and was aware that the filing of its ANDA and certification with respect to the '474 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Sun has infringed the '474 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205467 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '474 patent, including any applicable exclusivities or extensions;

C. That Sun, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States the Sun Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '474 patent prior to its expiration, including any exclusivities or extensions;

D. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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