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. _____
PRINSTON PHARMACEUTICAL, INC.,	)	
Defendant.	)	

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 Defendant Prinston Pharmaceutical, Inc. ("Prinston"), 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, Prinston is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. On information and belief, Prinston, directly or through its subsidiaries, is in the business of, among other things, developing, manufacturing, packaging,

and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions.

NATURE OF THE ACTION

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

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Prinston in Delaware because, upon information and belief, Prinston is a Delaware corporation with a registered agent in Delaware, American Incorporators Ltd., which is located at 1013 Centre Road Suite 403-A, Wilmington, DE 19805, and has availed itself of the rights and benefits of Delaware law. Further, upon information and belief, Prinston regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by selling pharmaceutical products in Delaware, directly or through its subsidiaries.

8. This Court has personal jurisdiction over Defendant Prinston by virtue of, *inter alia*, the fact that Prinston has 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 Plaintiff Takeda, a Delaware corporation.

Moreover, upon information and belief, Prinston has conducted business in Delaware, has derived substantial revenue therefrom, and has engaged in systematic, continuous, and pervasive contacts with the State of Delaware. This Court has personal jurisdiction over Prinston for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

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

THE PATENT-IN-SUIT

10. 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 duly and legally issued. A copy of the '474 patent is attached as Exhibit A.

11. 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

12. 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®."

13. 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.

14. Upon information and belief, Prinston submitted ANDA No. 206266 ("Prinston's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Prinston's ANDA 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 Prinston Generic Product") prior to the expiration of the '474 patent.

15. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Prinston certified in ANDA No. 206266 that no valid claim of the '474 patent will be infringed by the commercial manufacture, use, or sale of the Prinston Generic Product.

16. Plaintiffs received written notification of Prinston's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter ("Notice Letter"), dated May 22, 2014 and sent via certified U.S. mail.

17. Prinston's Notice Letter fails to comply with the requirement of 21 U.S.C. § 355(j)(2)(B)(iv)(II) because, *inter alia*, although it does not deny the existence of polymorphic crystal forms of febuxostat in the Prinston Generic Product, it contains limited information about the polymorphic crystal form or forms of febuxostat that may be present in the Prinston Generic Product.

18. Prinston's Notice Letter included an accompanying Offer of Confidential Access ("original OCA") to certain Prinston confidential information regarding the Prinston Generic Product. Plaintiffs subsequently, over the course of several weeks, negotiated with Prinston in an effort to agree on reasonable terms for Prinston's OCA. The parties were not able to reach agreement with respect to the revisions to the terms of Prinston's OCA that Plaintiffs proposed.

19. On June 19, 2014, Prinston's outside counsel informed Plaintiffs' outside counsel via electronic mail that "[f]or the avoidance of doubt, all prior offers of confidential access have been withdrawn."

20. On June 20, 2014, in another effort to resolve this issue, Plaintiffs' outside counsel informed Prinston's outside counsel that Plaintiffs were willing to accept the express terms of Prinston's original OCA.

21. On June 24, 2014, Prinston's outside counsel refused Plaintiffs' offer to agree to the express terms of Prinston's original OCA. Instead, Prinston premised any agreement on Prinston's original OCA on Plaintiffs' agreement to at least one additional "understanding" with respect to Prinston's original OCA. This "understanding" related to a term upon which the parties had previously been unable to reach agreement. On June 26, 2014, Plaintiffs' outside counsel informed Prinston's outside counsel that Plaintiffs could not agree to the additional "understanding" that Prinston was attempting to insert into the terms of its original OCA.

22. To date, Prinston has not provided Plaintiffs with a copy of any portions of its ANDA or any information regarding the Prinston Generic Product, beyond the information that was set forth in Prinston's Notice Letter.

23. The limited information relating to the Prinston Generic Product that was provided in Prinston's Notice Letter does not demonstrate that the Prinston Generic Product that Prinston is asking the FDA to approve for sale will not fall within the scope of any issued claim of the '474 patent.

24. Prinston's Notice Letter does not deny infringement of Claim 15 of the '474 patent, separate and apart from asserting invalidity.

25. Upon information and belief, Prinston will manufacture the Prinston Generic Product and/or febuxostat and release the Prinston Generic Product for distribution in the United States.

26. Upon information and belief, Prinston will market and sell the Prinston Generic Product in the United States.

27. Upon information and belief, Prinston's ANDA No. 206266 contains a "Paragraph III" certification with respect to U.S. Patent No. 5,614,520 ("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 OF U.S. PATENT NO. 6,225,474

28. Plaintiffs re-allege paragraphs 1-27 as if fully set forth herein.

29. Upon information and belief, Prinston's submission of ANDA No. 206266 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '474 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Prinston 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.

31. Upon information and belief, Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Prinston's ANDA No. 206266 be a date that is not earlier than the expiration of the term of the '474 patent, 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.

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

33. Upon information and belief, Prinston was aware of the existence of the '474 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '474 patent constituted an act of infringement of the '474 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Prinston 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. 206266 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 Prinston, 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 Prinston 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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