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. _____
RANBAXY LABORATORIES LIMITED, RANBAXY PHARMACEUTICALS, INC., and RANBAXY 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 Defendants Ranbaxy Laboratories Limited ("Ranbaxy Labs"), Ranbaxy Pharmaceuticals, Inc. ("RPI"), and Ranbaxy Inc. (collectively "Ranbaxy"), 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, Ranbaxy Labs is a company organized and existing under the laws of India, having its corporate headquarters at 12th Floor, Devika Towers,

6 Nehru Place, New Delhi, India. On information and belief, Ranbaxy Labs 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 and through those of its agents and operating subsidiaries, including RPI. On information and belief, Ranbaxy Labs has previously admitted that it is subject to this Court's jurisdiction. *See, e.g.*, *Forest Labs., Inc. v. Ranbaxy Inc.*, No. 13-cv-01607, D.I. 14 (D. Del. December 6, 2013); *Merck & Co., Inc. v. Ranbaxy Inc.*, No. 07-cv-00229, D.I. 10 (D. Del. June 21, 2007) and *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 07-cv-00138, D.I. 7 (D. Del. March 29, 2007). Ranbaxy Labs has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this judicial district. *See, e.g.*, *Merck & Co., Inc. v. Ranbaxy Inc.*, No. 07-cv-00229, D.I. 10 (D. Del. June 21, 2007) and *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 07-cv-00138, D.I. 7 (D. Del. March 29, 2007).

5. Upon information and belief, RPI is a company organized and existing under the laws of the state of Florida, having a principal place of business at 9431 Florida Mining Boulevard E, Jacksonville, FL 32257. On information and belief, RPI conducts the business of marketing generic pharmaceutical products and is engaged in the sale and distribution of generic versions of branded pharmaceutical products in the United States, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions and through those of its agents. RPI has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this judicial district. *See, e.g.*, *Pfizer Inc. v. Watson Pharms., Inc.*, No. 10-

00357, D.I. 26 (D. Del. July 16, 2010). On information and belief, RPI is a wholly-owned subsidiary of Ranbaxy Inc., a Delaware corporation.

6. Upon information and belief, Ranbaxy Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540. On information and belief, Ranbaxy Inc. conducts the business of marketing generic pharmaceutical products and is engaged in the sale and distribution of generic versions of branded pharmaceutical products in the United States, including in this judicial district and the State of Delaware through its own systematic, continuous, constant and pervasive actions and through those of its agents. On information and belief, Ranbaxy Inc. is an authorized agent for Ranbaxy Labs and/or other Ranbaxy entities. Ranbaxy Inc. has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g., Pfizer Inc. v. Watson Pharms., Inc.*, No. 10-00357, D.I. 26 (D. Del. July 16, 2010). On information and belief, Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Labs.

7. Upon information and belief, Ranbaxy Labs, RPI, and Ranbaxy Inc. through their own systematic, continuous, constant and pervasive actions and through those of their agents and operating subsidiaries, market, sell and/or distribute throughout the United States, including in this judicial district, generic versions of branded pharmaceutical products that Ranbaxy Labs manufactures or for which Ranbaxy Labs is the named applicant on approved ANDAs.

NATURE OF THE ACTION

8. 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

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

10. This Court has personal jurisdiction over Ranbaxy by virtue of, *inter alia*, the fact that it has committed, 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, having conducted business in Delaware and having derived substantial revenue therefrom, and having engaged in systematic, continuous, constant and pervasive contacts with the State of Delaware. This Court has personal jurisdiction over Ranbaxy for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. This Court has personal jurisdiction over Ranbaxy Labs because Ranbaxy Labs 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.*, *Merck & Co., Inc. v. Ranbaxy Inc.*, No. 07-cv-00229, D.I. 10 (D. Del. June 21, 2007) and *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 07-cv-00138, D.I. 7 (D. Del. March 29, 2007).

12. This Court has personal jurisdiction over Ranbaxy Labs because Ranbaxy Labs, either directly or through its subsidiaries or agents, has availed itself of the rights and benefits of Delaware law by incorporating Ranbaxy Inc. in Delaware.

13. This Court has personal jurisdiction over RPI 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., Pfizer Inc. v. Watson Pharms., Inc.*, No. 10-00357, D.I. 26 (D. Del. July 16, 2010).

14. This Court has personal jurisdiction over RPI because RPI, acting as the agent or wholly-owned subsidiary of Ranbaxy Labs, develops, manufactures, markets, sells and/or distributes many of its generic drugs in Delaware.

15. This Court has personal jurisdiction over RPI because RPI is a wholly-owned subsidiary of Ranbaxy Inc., a Delaware corporation.

16. This Court has personal jurisdiction over Ranbaxy Inc. 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., Pfizer Inc. v. Watson Pharms., Inc.*, No. 10-00357, D.I. 26 (D. Del. July 16, 2010).

17. This Court has personal jurisdiction over Ranbaxy Inc. because Ranbaxy Inc. is a Delaware corporation.

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

THE PATENT-IN-SUIT

19. 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

20. 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®."

21. 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.

22. Upon information and belief, Ranbaxy Labs submitted ANDA No. 205392 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("Ranbaxy's ANDA"). Upon information and belief, Ranbaxy Labs' ANDA No. 205392 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 "Ranbaxy Generic Product") prior to the expiration of the '474 patent.

23. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Ranbaxy Labs certified in ANDA No. 205392 that no valid claim of the '474 patent will be infringed by the commercial manufacture, use, or sale of the proposed Ranbaxy Generic Product.

24. Plaintiffs received written notification of Ranbaxy Labs' ANDA No. 205392 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated December 18, 2013 ("Notice Letter").

25. Ranbaxy Labs' Notice Letter does not deny infringement of claims 5 and 10 of the '474 patent separate and apart from asserting invalidity.

26. Upon information and belief, RPI will manufacture the Ranbaxy Generic Product and/or the febuxostat active pharmaceutical ingredient and release the Ranbaxy Generic Product for distribution in the U.S. market.

27. Ranbaxy Labs' Notice Letter does not provide any detailed statement with regard to the '520 patent. On information and belief, Ranbaxy Labs' ANDA No. 205392 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 RANBAXY 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, Ranbaxy Labs' submission of ANDA No. 205392 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 Ranbaxy Generic Product 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 relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Ranbaxy's ANDA No. 205392 be a date that is not earlier than the expiration of the '474 patent term, including any extensions 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 Ranbaxy'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, Ranbaxy 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 Ranbaxy 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. 205392 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 Ranbaxy, 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 Ranbaxy 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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