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. _____
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
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 Dr. Reddy's Laboratories, Limited ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") (collectively, "DRL"), 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 Dr. Reddy's Ltd. is an Indian public limited liability company, having a principal place of business at 7-1-27, Ameerpet,

Hyderabad, 500 016, Andhra Pradesh, India. Upon information and belief, Dr. Reddy's Ltd., itself and through its wholly owned subsidiary and agent Dr. Reddy's Inc., sells various drug products in the United States, including in this judicial district.

5. Upon information and belief, Defendant Dr. Reddy's Inc. is a New Jersey corporation, having a principal place of business at 200 Somerset Corporate Boulevard, 7th Floor, Bridgewater, New Jersey 08807. Upon information and belief, Dr. Reddy's Inc. sells various drug products in the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent Nos. 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

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

8. This Court has personal jurisdiction over both Dr. Reddy's Ltd. and Dr. Reddy's Inc. 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, a Delaware corporation. This Court has personal jurisdiction over both Dr. Reddy's Ltd. and Dr. Reddy's Inc. for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. This Court has personal jurisdiction over both Dr. Reddy's Ltd. and Dr. Reddy's Inc. because they have previously been sued in this district and have not challenged

personal jurisdiction, and have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Pfizer Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 09-00943; *Janssen Pharmaceutica N.V. et al. v. Dr. Reddy's Laboratories, Inc.*, No. 05-00380; and *Bayer AG et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 04-00179.

10. Upon information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. distribute numerous generic drugs for sale and use throughout the United States, including this judicial district.

11. This Court also has personal jurisdiction over both Dr. Reddy's Ltd. and Dr. Reddy's Inc., 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.

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

THE PATENT-IN-SUIT

13. 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

14. 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®."

15. 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.

16. Upon information and belief, DRL submitted ANDA No. 205374 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("DRL's ANDA"). Upon information and belief, DRL's ANDA No. 205374 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 DRL Generic Product") prior to the expiration of the '474 patent.

17. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, DRL certified in ANDA No. 205374 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 DRL Generic Product.

18. Plaintiffs received written notification of DRL's ANDA No. 205374 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated September 18, 2013 ("Notice Letter").

19. DRL'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 crystal forms of febuxostat, it contains limited information about the crystal form or forms of the materials for which DRL filed ANDA No. 205374.

20. Since receiving DRL's Notice Letter and the accompanying Offer of Confidential Access, while Plaintiffs have received DRL's ANDA, DRL did not provide a copy of its Drug Master File ("DMF"), though the ANDA makes reference to the DMF. Plaintiffs also requested samples of the DRL Generic Product, and though DRL agreed to provide samples, it

has not done so yet. Therefore, Plaintiffs have not had an opportunity to examine samples of DRL's Generic Product. The materials relating to the DRL Generic Product produced by DRL do not demonstrate that the product DRL is asking the FDA to approve for sale will not fall within the scope of an issued claim of the '474 patent.

21. DRL'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, DRL's ANDA No. 205374 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 DRL OF U.S. PATENT NO. 6,225,474

22. Plaintiffs re-allege paragraphs 1-21 as if fully set forth herein.

23. Upon information and belief, DRL's submission of ANDA No. 205374 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).

24. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the DRL Generic Product, if approved by the FDA, prior to the expiration of the '474 patent, including its patent term extension, would infringe the '474 patent under 35 U.S.C. § 271.

25. 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 DRL's ANDA No. 205374 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.

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

27. Upon information and belief, DRL 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 DRL 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. 205374 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 DRL, 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 DRL 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Bruce M. Wexler
Joseph M. O'Malley, Jr.
Jason T. Christiansen
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

Attorneys for Teijin Limited and Teijin Pharma Limited

William F. Cavanaugh, Jr.
Scott B. Howard
Zhiqiang Liu
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Takeda Pharmaceuticals U.S.A., Inc.

October 30, 2013