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. _____
ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LIMITED (d/b/a ZYDUS CADILA),	)	
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 Zydus Pharmaceuticals USA, Inc. ("Zydus USA") and Cadila Healthcare Ltd. d/b/a Zydus Cadila ("Zydus Cadila") (collectively "Zydus"), 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, Zydus USA is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 73

Route 31 North, Pennington, New Jersey, 08534. On information and belief, Zydus is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On further information and belief, Zydus has previously admitted that it is subject to this Court's jurisdiction and has previously submitted to this Court's jurisdiction. *See, e.g., Pfizer Inc. v. Zydus Pharms. (USA), Inc. and Cadila Healthcare Ltd. d/b/a Zydus Cadila*, No. 12-cv-00818, D.I. 9 (D. Del. July 20, 2012); *Pfizer Inc. v. Zydus Pharms. (USA), Inc.*, No. 13-cv-01154, D.I. 8 (D. Del. August 22, 2013); and *Alpex Pharma, S.A. v. Zydus Pharms. USA, Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila)*, No. 13-cv-01143, D.I. 24 (D. Del. October 7, 2013). Zydus 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. Zydus Pharms. (USA), Inc. and Cadila Healthcare Ltd. d/b/a Zydus Cadila*, No. 12-cv-00818, D.I. 9 (D. Del. July 20, 2012).

5. Upon information and belief, Zydus Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, 380015 Gujarat, India. On information and belief, Zydus Cadila is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including its wholly-owned subsidiary, Zydus USA. On information and belief, Zydus Cadila established Zydus USA for the purposes of distributing, marketing, offering for sale and/or selling its generic drug products throughout the United States, including this judicial district. On information and belief Zydus Cadila and Zydus USA work in concert with one another for purposes of developing, manufacturing, marketing, and selling generic drug products throughout the United States, including in this judicial district. On further

information and belief, Zydus Cadila has previously admitted that it is subject to this Court's jurisdiction and has previously submitted to this Court's jurisdiction. *See, e.g., Pfizer Inc. v. Zydus Pharms. (USA), Inc. and Cadila Healthcare Ltd. d/b/a Zydus Cadila*, No. 12-cv-00818, D.I. 9 (D. Del. July 20, 2012); and *Alpex Pharma, S.A. v. Zydus Pharms. USA, Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila)*, No. 13-cv-01143, D.I. 24 (D. Del. October 7, 2013). Zydus Cadila 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. Zydus Pharms. (USA), Inc. and Cadila Healthcare Ltd. d/b/a Zydus Cadila*, No. 12-cv-00818, D.I. 9 (D. Del. July 20, 2012).

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 7,361,676 ("the '676 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 Zydus 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, having conducted business in Delaware and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of Delaware. This Court has

personal jurisdiction over Zydus 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 Zydus USA and Zydus Cadila 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. v. Zydus Pharms. (USA), Inc. and Cadila Healthcare Ltd. d/b/a Zydus Cadila*, No. 12-cv-00818, D.I. 9 (D. Del. July 20, 2012); and *Alpex Pharma, S.A. v. Zydus Pharms. USA, Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila)*, No. 13-cv-01143, D.I. 24 (D. Del. October 7, 2013).

10. This Court has personal jurisdiction over Zydus Cadila and Zydus USA because upon information and belief, Zydus Cadila and Zydus USA regularly do business in Delaware and have 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 directly selling pharmaceutical products in Delaware. Upon information and belief, Zydus Cadila and Zydus USA have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

11. This Court has jurisdiction over Zydus USA because upon information and belief, Zydus USA distributes for sale hundreds of drug products throughout the United States, including in this judicial district. Upon information and belief, Zydus USA maintains a website, www.zydususa.com, advertising the drug products it markets and/or sells in the United States. The Zydus USA website lists seventy-one authorized distributors, including companies with extensive distribution networks in Delaware, such as CVS Pharmacy, Rite-Aid, Wal-Mart, and Walgreens. Walgreens, for example, has twenty-seven locations in Delaware.

12. Upon information and belief, Zydus sells drug products throughout the United States, including this judicial district.

13. This Court also has personal jurisdiction over Zydus 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 April 22, 2008, the '676 patent, titled "Solid Preparation Containing Single Crystal Form," was issued. A copy of the '676 patent is attached as Exhibit A. Teijin Ltd. is the owner of the '676 patent. Teijin Pharma Ltd. and Takeda hold exclusive licenses with respect to the '676 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 '676 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, Zydus USA submitted ANDA No. 205443 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("Zydus's ANDA"). Upon information and belief, Zydus USA's ANDA No. 205443 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 Zydus Generic Product") prior to the expiration of the '676 patent.

19. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Zydus certified in ANDA No. 205443 that no valid claim of the '676 patent will be infringed by the commercial manufacture, use, or sale of the proposed Zydus Generic Product.

20. Plaintiffs received written notification of Zydus's ANDA No. 205443 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated November 11, 2013 ("Notice Letter").

21. Zydus USA'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 admits the existence of crystal A of 2-(3-cyano-4-isobutyloxyphenyl)-4-methyl-5-thiazolecarboxylic acid in the Zydus Generic Product, it contains limited information about the average particle diameter of the crystal A in the Zydus Generic Product for which Zydus USA filed ANDA No. 205443 and acknowledges that the data relied on in its Notice Letter is "pre-tableting" data.

22. Since receiving Zydus USA's Notice Letter and the accompanying Offer of Confidential Access ("OCA"), Plaintiffs have negotiated with Zydus USA to obtain Zydus USA's ANDA, but Plaintiffs received that ANDA less than five business days prior to the expiration of the 45-day period to file suit. Further, Zydus USA did not provide a copy of its Drug Master File ("DMF"), though the ANDA makes reference to the DMF. The materials relating to the Zydus Generic Product produced by Zydus USA do not demonstrate that the product Zydus USA is asking the FDA to approve for sale will not fall within the scope of an issued claim of the '676 patent.

23. Upon information and belief, Zydus Cadila will manufacture the Zydus Generic Product and/or API and release the Zydus Generic Product for distribution in the U.S. market. *See* http://www.medguideindia.com/ and http://kelo.in/category/febuxostat/ (both naming Zydus Cadila as the manufacturer of Zydus's generic febuxostat tablets.)

24. Zydus'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, Zydus's ANDA No. 205443 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 ZYDUS OF U.S. PATENT NO. 7,361,676

25. Plaintiffs re-allege paragraphs 1-24 as if fully set forth herein.

26. Upon information and belief, Zydus USA's submission of ANDA No. 205443 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '676 patent under 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Zydus Generic Product, if approved by the FDA, prior to the expiration of the '676 patent, including any applicable exclusivities or extensions, would infringe the '676 patent under 35 U.S.C. § 271.

28. 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 Zydus USA's ANDA No. 205443 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 '676 patent to which Plaintiffs are or become entitled.

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

30. Upon information and belief, Zydus was aware of the existence of the '676 patent and was aware that the filing of its ANDA and certification with respect to the '676 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Zydus has infringed the '676 patent;

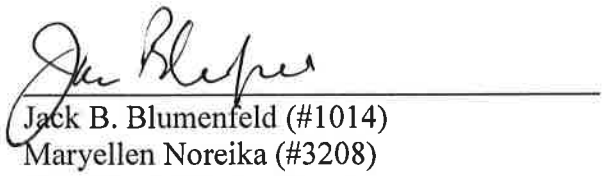
B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205443 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '676 patent, including any applicable exclusivities or extensions;

C. That Zydus, 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 Zydus Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '676 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



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