IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| TEIJIN LIMITED, TEIJIN PHARMA LIMITED, and TAKEDA PHARMACEUTICALS U.S.A., INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| HETERO USA, INC. and HETERO LABS LTD. | ) | |
| 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 Hetero USA, Inc. ("Hetero USA"), and Hetero Labs Ltd., ("Hetero Labs") (collectively, "Hetero"), 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, Hetero USA is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey, 08854. On information and belief, Hetero

USA conducts the business of making and selling 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 further information and belief, Hetero USA has previously admitted that it is subject to this Court's jurisdiction. *See, e.g., Forest Laboratories Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, No. 12-cv-00305-SLR, D.I. 47 (D. Del. June 4, 2012); *AbbVie Inc. v. Hetero USA Inc. et al.*, No. 13-cv-00852-RGA, D.I. 18 (D. Del. July 30, 2013); *UCB Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01213-LPS, D.I. 14 (D. Del. September 13, 2013); *Eisai Co. Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01280-LPS, D.I. 14 (D. Del. September 27, 2013); *Forest Laboratories Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01603-SLR, D.I. 14 (D. Del. November 22, 2013); and *Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01091-LPS, D.I. 15 (D. Del. October 3, 2013). Hetero USA 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., Forest Laboratories Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, No. 12-cv-305-SLR, D.I. 47 (D. Del. June 4, 2012); *AbbVie Inc. v. Hetero USA Inc. et al.*, No. 13-cv-00852-RGA, D.I. 18 (D. Del. July 30, 2013); *UCB Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01213-LPS, D.I. 14 (D. Del. September 13, 2013); *Eisai Co. Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01280-LPS, D.I. 14 (D. Del. September 27, 2013); *Forest Laboratories Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01603-SLR, D.I. 14 (D. Del. November 22, 2013); *Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01091-LPS, D.I. 15 (D. Del. October 3, 2013).

5. Upon information and belief, defendant Hetero Labs is an Indian corporation, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, 500 018, A.P. India. On information and belief, Hetero

Labs is in the business of, among other things, developing, manufacturing, marketing 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 its wholly-owned subsidiary, Hetero USA. On information and belief, Hetero Labs established Hetero USA for the purposes of distributing, marketing, offering for sale and/or selling its generic versions of branded pharmaceutical products throughout the United States, including this judicial district. On information and belief, Hetero Labs and Hetero USA work in concert with one another for purposes of developing, manufacturing, marketing, and selling generic versions of branded pharmaceutical products throughout the United States, including in this judicial district. On further information and belief, Hetero Labs has previously admitted that it is subject to this Court's jurisdiction. *See, e.g., Forest Laboratories Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, No. 12-cv-00305-SLR, D.I. 47 (D. Del. June 4, 2012); *AbbVie Inc. v. Hetero USA Inc. et al.*, No. 13-cv-00852-RGA, D.I. 18 (D. Del. July 30, 2013); *UCB Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01213-LPS, D.I. 14 (D. Del. September 13, 2013); *Eisai Co. Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01280-LPS, D.I. 14 (D. Del. September 27, 2013); *Forest Laboratories Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01603-SLR, D.I. 14 (D. Del. November 22, 2013); and *Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01091-LPS, D.I. 15 (D. Del. October 3, 2013). Hetero 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., Forest Laboratories Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, No. 12-cv-305-SLR, D.I. 47 (D. Del. June 4, 2012); *AbbVie Inc. v. Hetero USA Inc. et al.*, No. 13-cv-00852-RGA, D.I. 18 (D. Del. July 30, 2013); *UCB Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01213-LPS, D.I. 14 (D. Del. September 13, 2013); *Eisai Co. Ltd. et al. v. Hetero USA*

*Inc. et al.*, No. 13-cv-01280-LPS, D.I. 14 (D. Del. September 27, 2013); *Forest Laboratories Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01603-SLR, D.I. 14 (D. Del. November 22, 2013); *Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01091-LPS, D.I. 15 (D. Del. October 3, 2013).

## NATURE OF THE ACTION

6. 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

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 Hetero USA by virtue of, *inter alia*, the fact that Hetero USA 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 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 Hetero USA 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 Hetero USA because Hetero USA has previously been sued in this district and has not challenged personal jurisdiction, and Hetero USA has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Forest Laboratories Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, No. 12-cv-305-SLR, D.I. 47 (D. Del. June 4, 2012); *AbbVie Inc.*

*v. Hetero USA Inc. et al.*, No. 13-cv-00852-RGA, D.I. 18 (D. Del. July 30, 2013); *UCB Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01213-LPS, D.I. 14 (D. Del. September 13, 2013); *Eisai Co. Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01280-LPS, D.I. 14 (D. Del. September 27, 2013); *Forest Laboratories Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01603-SLR, D.I. 14 (D. Del. November 22, 2013); *Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01091-LPS, D.I. 15 (D. Del. October 3, 2013).

10. This Court has personal jurisdiction over Hetero Labs by virtue of, *inter alia*, the fact that Hetero Labs 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 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 Hetero Labs 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 Hetero Labs because Hetero Labs has previously been sued in this district and has not challenged personal jurisdiction, and Hetero Labs has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Forest Laboratories Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, No. 12-cv-305-SLR, D.I. 47 (D. Del. June 4, 2012); *AbbVie Inc. v. Hetero USA Inc. et al.*, No. 13-cv-00852-RGA, D.I. 18 (D. Del. July 30, 2013); *UCB Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01213-LPS, D.I. 14 (D. Del. September 13, 2013); *Eisai Co. Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01280-LPS, D.I. 14 (D. Del. September 27, 2013); *Forest Laboratories Inc. et al. v. Hetero USA Inc. et al.*, No. 13-cv-

01603-SLR, D.I. 14 (D. Del. November 22, 2013); *Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc. et al.*, No. 13-cv-01091-LPS, D.I. 15 (D. Del. October 3, 2013).

12. This Court has jurisdiction over Hetero USA because, upon information and belief, Hetero USA distributes drug products for sale throughout the United States, including in this judicial district.

13. Upon information and belief, Hetero USA sells drug products throughout the United States, including this judicial district.

14. This Court also has personal jurisdiction over Hetero USA by virtue of, *inter alia*, the fact that Hetero USA has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with the State.

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

## THE PATENT-IN-SUIT

16. On May 1, 2001, the United States Patent and Trademark Office ("PTO") issued the '474 patent, titled "Polymorphs of 2-(3-cyano-4-isobutyloxyphenyl)-4-methyl-5-thiazolecarboxylic acid and method of producing the same." 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

17. 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®."

18. 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.

19. Upon information and belief, Hetero submitted ANDA No. 205344 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("Hetero's ANDA"). Upon information and belief, Hetero's ANDA No. 205344 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 Hetero Generic Product") prior to the expiration of the '474 patent.

20. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Hetero certified in ANDA No. 205344 that no valid claim of the '474 patent will be infringed by the commercial manufacture, use, offer for sale, sale or importation of the proposed Hetero Generic Product. In its Notice Letter, Hetero further alleged that the '474 patent is invalid, unenforceable, and/or will not be infringed.

21. Hetero's Notice Letter fails to comply with the requirement of 21 U.S.C. § 355(j)(2)(B)(iv)(II) because, *inter alia*, it contains limited information about the crystal form or forms of the materials for which Hetero filed ANDA No. 205344.

22. Since receiving Hetero's Notice Letter and the accompanying Offer of Confidential Access, Plaintiffs have negotiated with Hetero to obtain Hetero's ANDA, but Hetero did not provide a copy of its Drug Master File ("DMF"), though the ANDA makes reference to the DMF. The materials relating to the Hetero Generic Product produced by Hetero do not demonstrate that the product Hetero is asking the FDA to approve for sale will not fall within the scope of an issued claim of the '474 patent.

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

24. Hetero'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, Hetero's ANDA No. 205344 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 HETERO OF U.S. PATENT NO. 6,225,474**

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

26. Upon information and belief, Hetero's submission of ANDA No. 205344 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).

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

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 Hetero's ANDA No. 205344 be a date that is not earlier than the expiration of the '474 patent term including any extensions granted by the PTO 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.

29. Plaintiffs will be irreparably harmed by Hetero'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, Hetero 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 infringement of that patent.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Hetero 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. 205344 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 Hetero, 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 Hetero 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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February 7, 2014