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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED, Plaintiffs, v. MICRO LABS USA, INC. AND MICRO LABS LTD., Defendants.	Civil Action No.____

COMPLAINT

Plaintiffs Takeda GmbH ("Takeda"), AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca") (Takeda and AstraZeneca, collectively, "Plaintiffs"), by its attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Micro Labs USA, Inc. and Micro Labs Ltd. (collectively, "Micro Labs"). This action relates to Abbreviated New Drug

Application ("ANDA") No. 208180 filed by Micro Labs with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 208180, Micro Labs seeks approval to market 500 mcg tablets of roflumilast, generic versions of Plaintiffs' Daliresp® drug product (the "Micro Labs ANDA product"), prior to expiration of U.S. Patent No. 5,712,298 (the "'298 patent").

PARTIES

3. Takeda GmbH is a corporation organized and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Strasse 2, 78467 Konstanz, Germany.

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

5. AstraZeneca UK Limited is a company incorporated under the Laws of England and Wales, having a registered office at 2 Kingdom Street, London, England W2 6BD.

6. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for Chronic Obstructive Pulmonary Disease ("COPD"). AstraZeneca markets and sells Daliresp® in this judicial district and throughout the United States.

7. Upon information and belief, Micro Labs USA, Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 104 Carnegie Center, Suite 216, Princeton, New Jersey 08540.

8. Upon information and belief, Micro Labs Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 27, Race Course Road, Bangalore 560 001, India.

9. Upon information and belief, Micro Labs USA, Inc. is a wholly-owned subsidiary of Micro Labs Ltd.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

12. This Court has jurisdiction over Micro Labs because, upon information and belief, Micro Labs USA, Inc. is a New Jersey corporation with its principal place of business in New Jersey and is the subsidiary and agent of Micro Labs Ltd. Upon information and belief, Micro Labs USA, Inc. is acting as the agent of Micro Labs Ltd. with respect to ANDA No. 208180.

13. In the alternative, this Court has jurisdiction over Micro Labs Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

14. This Court also has jurisdiction over Micro Labs because, *inter alia*, this action arises from actions of Micro Labs directed toward New Jersey, and because Micro Labs has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. Upon information and belief, Micro Labs regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates. Upon information and belief, Micro Labs derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

15. This Court also has jurisdiction over Micro Labs USA, Inc. because, *inter alia*, upon information and belief, Micro Labs USA, Inc. is a New Jersey corporation and its principal

place of business is located in Princeton, New Jersey. Upon information and belief, Micro Labs USA, Inc., directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

16. Micro Labs has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction, including in the case captioned *Takeda GmbH et al. v. Micro Labs USA, Inc. et al.*, No. 3:15-cv-3376 (D.N.J. filed May 15, 2015), and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey.

17. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Micro Labs.

PATENT-IN-SUIT

18. On January 27, 1998, the U.S. Patent and Trademark Office duly and legally issued the '298 patent, titled "Fluoroalkoxy-Substituted Benzamides And Their Use As Cyclic Nucleotide Phosphodiestrerase Inhibitors." A true and correct copy of the '298 patent is attached hereto as Exhibit A. The claims of the '298 patent are valid and enforceable. Takeda is the owner of the '298 patent and has the right to enforce it. The expiration date of the '298 patent is January 27, 2020.

19. AstraZeneca UK Limited is the exclusive licensee of the '298 patent in the United States. AstraZeneca UK Limited is also the holder of New Drug Application ("NDA") No. 022522, by which the FDA granted approval for the marketing and sale of 500 mcg strength roflumilast tablets. AstraZeneca markets roflumilast tablets in the United States, under the trade name "Daliresp®". The FDA's official publication of approved drugs (the "Orange Book") includes Daliresp® together with the '298 patent. Daliresp® is approved as a treatment to reduce the risk of COPD exacerbation in patients with severe COPD associated with chronic

bronchitis and a history of exacerbation. A copy of the complete prescribing information for Daliresp® approved in NDA No. 022522 is attached as Exhibit B.

20. AstraZeneca Pharmaceuticals LP is authorized by the patent licensee, AstraZeneca UK Limited, to market and distribute Daliresp® in the United States.

INFRINGEMENT BY MICRO LABS

21. By letter sent by Federal Express on October 15, 2015, Micro Labs notified Takeda GmbH and Forest Pharmaceuticals, Inc., Forest Laboratories, LLC, and Forest Research Institute (collectively, "Forest") that Micro Labs had submitted ANDA No. 208180 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Daliresp Notice Letter"). Takeda and Forest received the Daliresp Notice Letter no earlier than October 16, 2015.

22. The Daliresp Notice Letter states that Micro Labs seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Micro Labs ANDA product before the expiration of the '298 patent. Upon information and belief, Micro Labs intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Micro Labs ANDA product promptly upon receiving FDA approval to do so.

23. By filing ANDA No. 208180, Micro Labs has necessarily represented to the FDA that the Micro Labs ANDA product has the same active ingredient as Daliresp®, has the same method of administration, dosage form, and strength as Daliresp®, and is bioequivalent to Daliresp®.

24. In the Daliresp Notice Letter, Micro Labs states that its ANDA contains a Paragraph IV certification asserting that the '298 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Micro Labs ANDA product.

25. In the Daliresp Notice Letter, Micro Labs offered confidential access to portions of its ANDA No. 208180 on terms and conditions set forth in the Daliresp Notice Letter ("the Micro Labs Offer"). Micro Labs requested that Plaintiffs accept the Micro Labs Offer before receiving access to Micro Labs's ANDA No. 208180. The Micro Labs Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Micro Labs Offer contained a broad patent prosecution bar and unreasonably limited access to outside counsel only, thereby preventing outside counsel from seeking the opinion of objective experts or discussing relevant findings with Plaintiffs. The restrictions Micro Labs has placed on access to ANDA No. 208180 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

26. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Daliresp Notice Letter.

COUNT I

(INFRINGEMENT OF THE '298 PATENT)

27. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth herein.

28. Micro Labs's submission of ANDA No. 208180 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Micro Labs ANDA product prior to the expiration of the '298 patent constituted a technical act of infringement of one or more of the claims of the '298 patent under 35 U.S.C. § 271(e)(2)(A).

29. Micro Labs's commercial manufacture, use, offer to sell, sale, or importation of the Micro Labs ANDA product prior to the expiration of the '298 patent, and its inducement of and/or contribution to such conduct, would further infringe one or more claims of the '298 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

30. Upon FDA approval of Micro Labs's ANDA No. 208180, Micro Labs will infringe one or more claims of the '298 patent by making, using, offering to sell, and selling the Micro Labs ANDA product in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '298 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

31. If Micro Labs's marketing and sale of the Micro Labs ANDA product prior to expiration of the '298 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the '298 patent are not invalid, are not unenforceable, and are infringed by Micro Labs's submission of ANDA No. 208180, and that Micro Labs's making, using, offering to sell, or selling in the United States, or importing into the United States the Micro Labs ANDA product will infringe the '298 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 208180 shall be a date which is not earlier than the expiration date of the '298 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert

with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Micro Labs ANDA product until after the expiration date of the '298 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief to Plaintiffs if Micro Labs engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Micro Labs ANDA product prior to the expiration date of the '298 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: November 5, 2015

Respectfully Submitted,

/s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited, by their undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending actions:

- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd.*, No. 3:15-cv-03375-FLW-DEA (D.N.J.);
- *Micro Labs USA, Inc. and Micro Labs Ltd.*, No. 3:15-cv-03376-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Zydus Pharmaceuticals (USA) Inc.*, No. 3:15-cv-03377-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Strides Pharma, Inc. and Strides Pharma Global PTE Limited*, No. 3:15-cv-03378-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Apotex Corp. and Apotex Inc.*, No. 3:15-cv-03379-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Prinston Pharmaceutical, Inc.*, No. 3:15-cv-03330-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Breckenridge Pharmaceutical Inc.*, No. 3:15-cv-03382-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Citron Pharma LLC and MSN Laboratories Private Limited*, No. 3:15-cv-03383-FLW-DEA (D.N.J.);
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Mylan Pharmaceuticals Inc.*, No. 3:15-cv-03384-FLW-DEA (D.N.J.); and
- *Takeda GmbH, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Hetero Labs Limited Unit-III, and Hetero Labs Limited*, No. 3:15-cv-03385-FLW-DEA.

Dated: November 5, 2015

Respectfully Submitted,

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