**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**



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| TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED,<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN PHARMACEUTICALS INC.,<br><br>Defendant. | Civil Action No. 1:15cv93 |

## 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 Defendant Mylan Pharmaceuticals Inc. ("Mylan"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208257 filed by Mylan with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 208257, Mylan seeks approval to market 500 mcg tablets of roflumilast, generic versions of Plaintiffs' Daliresp® drug product (the "Mylan ANDA product"), prior to expiration of U.S. Patent Nos. 5,712,298 (the "'298 patent"); 8,536,206 (the "'206 patent"); 8,604,064 (the "'064 patent"); and 8,618,142 (the "'142 patent") (collectively, the "patents-in-suit").

## 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, Mylan is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

## JURISDICTION AND VENUE

8. 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.

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

10. This Court has jurisdiction over Mylan because, upon information and belief, Mylan is a company organized and existing under the laws of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505

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

**PATENTS-IN-SUIT**

12. 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 current expiration date of the '298 patent is January 27, 2016, but Plaintiffs anticipate an additional patent term extension through at least January 27, 2020.

13. On September 17, 2013, the U.S. Patent and Trademark Office duly and legally issued the '206 patent, titled "Process For The Preparation Of Roflumilast." A true and correct copy of the '206 patent is attached hereto as Exhibit B. The claims of the '206 patent are valid and enforceable. Takeda is the owner of the '206 patent and has the right to enforce it. The expiration date of the '206 patent is March 8, 2024.

14. On December 10, 2013, the U.S. Patent and Trademark Office duly and legally issued the '064 patent, titled "Process For The Preparation Of Roflumilast." A true and correct copy of the '064 patent is attached hereto as Exhibit C. The claims of the '064 patent are valid and enforceable. Takeda is the owner of the '064 patent and has the right to enforce it. The expiration date of the '064 patent is March 8, 2024.

15. On December 31, 2013, the U.S. Patent and Trademark Office duly and legally issued the '142 patent, titled "Process For The Preparation Of Roflumilast." A true and correct copy of the '142 patent is attached hereto as Exhibit D. The claims of the '142 patent are valid

and enforceable. Takeda is the owner of the '142 patent and has the right to enforce it. The expiration date of the '142 patent is March 8, 2024.

16. AstraZeneca UK Limited is the exclusive licensee of the patents-in-suit 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 patents-in-suit. 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 E.

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

## INFRINGEMENT BY MYLAN

18. By letter sent by Federal Express on April 14, 2015, Mylan notified Plaintiffs that Mylan had submitted ANDA No. 208257 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"). Plaintiffs received the Daliresp Notice Letter no earlier than April 16, 2015.

19. The Daliresp Notice Letter states that Mylan seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Mylan ANDA product before the expiration of the patents-in-suit. Upon information and belief, Mylan intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Mylan ANDA product promptly upon receiving FDA approval to do so.

20. By filing ANDA No. 208257, Mylan has necessarily represented to the FDA that the Mylan 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®.

21. In the Daliresp Notice Letter, Mylan states that its ANDA contains a Paragraph IV certification asserting that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Mylan ANDA product.

22. In the Daliresp Notice Letter, Mylan offered confidential access to portions of its ANDA No. 208257 on terms and conditions set forth in the Daliresp Notice Letter ("the Mylan Offer"). Mylan requested that Plaintiffs accept the Mylan Offer before receiving access to Mylan's ANDA No. 208257. The Mylan Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Mylan 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 Mylan has placed on access to ANDA No. 208257 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).

23. 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)

24. Each of the preceding paragraphs 1 to 23 is incorporated as if fully set forth herein.

25. Mylan's submission of ANDA No. 208257 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan 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).

26. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan 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).

27. Upon FDA approval of Mylan's ANDA No. 208257, Mylan will infringe one or more claims of the '298 patent by making, using, offering to sell, and selling the Mylan 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.

28. If Mylan's marketing and sale of the Mylan 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.

## COUNT II

## (INFRINGEMENT OF THE '206 PATENT)

29. Each of the preceding paragraphs 1 to 28 is incorporated as if fully set forth herein.

30. Mylan's submission of ANDA No. 208257 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA product for the same treatment claimed in the '206 patent prior to the expiration of the '206 patent constituted a technical act of infringement of one or more of the claims of the '206 patent under 35 U.S.C. § 271(e)(2)(A).

31. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product for the same treatment claimed in the '206 patent prior to the expiration of the '206 patent, and its inducement of and/or contribution to such conduct, would further infringe one or more claims of the '206 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

32. Upon FDA approval of Mylan's ANDA No. 208257, Mylan will infringe one or more claims of the '206 patent by making, using, offering to sell, and selling the Mylan ANDA product for the same treatment claimed in the '206 patent in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '206 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

33. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '206 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

## COUNT III

## (INFRINGEMENT OF THE '064 PATENT)

34. Each of the preceding paragraphs 1 to 33 is incorporated as if fully set forth herein.

35. Mylan's submission of ANDA No. 208257 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA product for the same treatment claimed in the '064 patent prior to the expiration of the '064 patent constituted a technical act of infringement of one or more of the claims of the '064 patent under 35 U.S.C. § 271(e)(2)(A).

36. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product for the same treatment claimed in the '064 patent prior to the expiration of the '064 patent, and its inducement of and/or contribution to such conduct, would further infringe one or more claims of the '064 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

37. Upon FDA approval of Mylan's ANDA No. 208257, Mylan will infringe one or more claims of the '064 patent by making, using, offering to sell, and selling the Mylan ANDA product for the same treatment claimed in the '064 patent in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '064 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

38. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '064 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT IV**

**(INFRINGEMENT OF THE '142 PATENT)**

39. Each of the preceding paragraphs 1 to 38 is incorporated as if fully set forth herein.

40. Mylan's submission of ANDA No. 208257 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA product prior to the expiration of the '142 patent constituted a technical act of infringement of one or more of the claims of the '142 patent under 35 U.S.C. § 271(e)(2)(A).

41. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product prior to the expiration of the '142 patent, and its inducement of and/or contribution to such conduct, would further infringe one or more claims of the '142 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

42. Upon FDA approval of Mylan's ANDA No. 208257, Mylan will infringe one or more claims of the '142 patent by making, using, offering to sell, and selling the Mylan 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 '142 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

43. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '142 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 patents-in-suit are not invalid, are not unenforceable, and are infringed by Mylan's submission of ANDA No. 208257, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States the Mylan ANDA product will infringe the patents-in-suit.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 208257 shall be a date which is not earlier than the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Mylan, 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 Mylan ANDA product until after the latest expiration date of the patents-in-suit, 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 Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mylan ANDA product prior to the latest expiration date of the patents-in-suit, 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: May 27, 2015

SCHRADER, BYRD & COMPANION, PLLC

*/s/ James F. Companion*

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