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

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD. Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN, INC. Defendants.	C.A. No. 1:16-CV-93

COMPLAINT

Plaintiffs Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. (collectively, "Plaintiffs") by their 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. This action relates to Abbreviated New Drug Application ("ANDA") No. 208005 filed by Mylan Pharmaceuticals Inc. with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of Fingolimod 0.5 mg capsules, a generic version of Novartis's GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent No. 5,604,229 ("the '229 patent").

PARTIES

2. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

3. Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

4. Mitsubishi Tanabe Pharma Corporation ("MTPC") is a corporation organized and existing under the laws of Japan, having an office and place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka, 541-8505, Japan.

5. Mitsui Sugar Co., Ltd. ("Mitsui") is a corporation organized and existing under the laws of Japan, having an office and place of business at 36-2, Nihonbashi-Hakozakicho, Chuo-ku, Tokyo, Japan.

6. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

7. Upon information and belief, Mylan Inc. itself, and through its wholly-owned subsidiary and agent, Mylan Pharmaceuticals Inc., develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

8. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

9. Upon information and belief, Mylan Pharmaceuticals Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc. and is controlled and/or dominated by Mylan Inc. Upon information and belief, Mylan Pharmaceuticals Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Mylan Inc. Upon information and belief, Mylan Inc. established Mylan Pharmaceuticals Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

10. Upon information and belief, and consistent with their past practices, Mylan Inc. and Mylan Pharmaceuticals Inc. acted collaboratively in the preparation and submission of ANDA No. 208005.

11. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 208005, Mylan Inc. and Mylan Pharmaceuticals Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208005 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

12. NPC and Novartis AG are collectively referred to hereafter as "Novartis."

13. Mylan Inc. and Mylan Pharmaceuticals Inc. are collectively referred to hereafter as "Mylan," unless otherwise noted.

JURISDICTION AND VENUE

14. 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 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

15. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. because, upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

16. This Court has personal jurisdiction over Mylan Inc. because, among other reasons: (1) it has extensive contacts with the State of West Virginia, including through its subsidiary Mylan Pharmaceuticals Inc.; (2) regularly does business in this district, including through its subsidiary Mylan Pharmaceuticals Inc.; and (3) on information and belief, is registered with the West Virginia Secretary of State to do business in West Virginia and has appointed a registered agent in West Virginia (located at Corporation Service Company, 209 West Washington St., Charleston, WV 25302) for the receipt of service of process.

17. This Court also has personal jurisdiction over Mylan because it has availed itself of the legal protections of the State of West Virginia by, among other things, selecting the State of West Virginia as the place of incorporation for Mylan Pharmaceuticals Inc. and by consenting to jurisdiction and/or asserting counterclaims in prior cases filed in this district under the Hatch-Waxman Act. *See, e.g.*, *Novartis Pharm. Co. et al v. Mylan Pharm. Inc. et al*, No. 1:14-cv-111-IMK (N.D.W. Va. December 4, 2014); *Teva Pharm.USA, Inc. et al v. Mylan Pharm. Inc. et al*, No. 1:14-cv-167-IMK (N.D.W. Va. November 26, 2014); *Acorda Therapeutics, Inc. et al v. Mylan Pharm. Inc. et al*, No. 1:14-cv-139-IMK (N.D.W. Va. January

12, 2015); *Pfizer Inc. et al v. Mylan Inc. et al*, No. 1:15-cv-4-IMK (N.D.W. Va. February 13, 2015); *Noven Pharm., Inc. et al v. Mylan Tech., Inc. et al*, No. 1:15-cv-69-IMK-MJA (N.D.W. Va. May 4, 2015).

18. 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.

THE PATENT-IN-SUIT AND GILENYA®

19. On February 18, 1997, the U.S. Patent and Trademark Office duly and legally issued the '229 patent, entitled "2-Amino-1,3-Propanediol Compound and Immunosuppressant." A true and correct copy of the '229 patent is attached hereto as **Exhibit A**. The claims of the '229 patent are valid and enforceable. The '229 patent is owned by Mitsui and MTPC and exclusively licensed to Novartis. Plaintiffs have the right to sue for and obtain equitable relief and damages for infringement of the '229 patent.

20. NPC is the holder of New Drug Application ("NDA") No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability in patients with relapsing forms of multiple sclerosis. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

21. GILENYA® and the use of GILENYA® is covered by one or more claims of the '229 patent.

22. The FDA's official publication of approved drugs (the "Orange Book") lists the '229 patent in connection with GILENYA®.

INFRINGEMENT BY MYLAN OF THE PATENT-IN-SUIT

23. Plaintiffs incorporate each of the proceeding paragraphs 1 - 22 as if fully set forth herein.

24. By letters dated April 6, 2016, ("the Notice Letters"), Mylan Pharmaceuticals Inc. notified Plaintiffs that Mylan Pharmaceuticals Inc. had submitted to the FDA ANDA No. 208005 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Mylan's ANDA Product"). The purpose of Mylan's submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '229 patent.

25. In the Notice Letters, Mylan Pharmaceuticals Inc. notified Plaintiffs that, as a part of its ANDA, Mylan had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '229 patent asserting that the '229 is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Mylan's ANDA Product.

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

27. By filing ANDA No. 208005, Mylan has necessarily represented to the FDA that, upon approval, Mylan's ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as GILENYA®, and will be bioequivalent to GILENYA®.

28. Mylan's submission of ANDA No. 208005 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Mylan's ANDA Product, prior to the

expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, Mylan had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 208005 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

30. Upon information and belief, Mylan intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208005.

31. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '229 patent.

32. Upon information and belief, use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '229 patent.

33. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '229 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

34. Upon information and belief, Mylan knows that Mylan's ANDA Product is especially made or adapted for use in infringing the '229 patent, and that Mylan's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 208005.

35. The foregoing acts by Mylan constitute and/or will constitute infringement of the '229 patent, active inducement of infringement of the '229 patent, and/or contribution to the infringement by others of the '229 patent.

36. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '229 patent, active inducement of infringement of the '229 patent, and/or contribution to the infringement by others of the '229 patent.

37. If Mylan's infringement of the '229 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more claims of the '229 patent is not invalid, is enforceable and is infringed by Mylan's submission of ANDA No. 208005, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States of Mylan's ANDA Product, will infringe the '229 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. 208005 shall be a date which is not earlier than the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes 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 Mylan's ANDA Product, until after the expiration date of the '229 patent,

including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. Damages or other monetary relief to Novartis if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Mylan's ANDA Product, prior to the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes 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 18, 2015

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