IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD. Plaintiffs, v. ACTAVIS, INC. and ACTAVIS ELIZABETH LLC Defendants.	C.A. No. _____

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. 207972 filed by Actavis Elizabeth LLC with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of Fingolimod Hydrochloride Capsules, Eq. 0.5 mg Base, 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 2-6-18, Kitahama, 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 103-8423, Tokyo, Japan.

6. Upon information and belief, Actavis Inc. is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. Upon information and belief, Actavis Inc. itself, and through its wholly-owned subsidiary and agent, Actavis Elizabeth LLC, 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, Actavis Elizabeth LLC is a company organized and existing under the laws of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

9. Upon information and belief, Actavis Elizabeth LLC 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, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis Inc. and is controlled and/or dominated by Actavis Inc. Upon information and belief, Actavis Elizabeth LLC 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 Actavis Inc. Upon information and belief, Actavis Inc. established Actavis Elizabeth LLC 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, Actavis Inc. and Actavis Elizabeth LLC acted collaboratively in the preparation and submission of ANDA No. 207972.

11. Upon information and belief, and consistent with its past practices, Actavis Elizabeth LLC's preparation and submission of ANDA No. 207972 was done at the direction, under the control, and for the direct benefit of Actavis Inc.

12. Upon information and belief, and consistent with their past practices, Actavis Inc. directed Actavis Elizabeth LLC to submit ANDA No. 207972, in whole or in part, to shield Actavis Inc. from liability for patent infringement based upon that act.

13. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207972, Actavis Inc. and Actavis Elizabeth LLC 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. 207972 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

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

15. Actavis Inc. and Actavis Elizabeth LLC are collectively referred to hereafter as "Actavis."

JURISDICTION AND VENUE

16. 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).

17. This Court has personal jurisdiction over Actavis because, among other things, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 207972 that has led to foreseeable harm and injury to NPC, a Delaware corporation.

18. This Court also has personal jurisdiction over Actavis because its activities (*e.g.*, filing ANDA No. 207972 and sending notice of a paragraph IV certification) were purposefully directed to the state of Delaware, where Plaintiff NPC is organized. As a result, the consequences of Actavis's actions were (and will be) suffered in Delaware.

19. This Court also has personal jurisdiction over Actavis because its affiliations with the State of Delaware, including by virtue of the incorporation of Actavis Elizabeth LLC in Delaware, are so continuous and systematic as to render it essentially at home in this forum.

20. This Court also has personal jurisdiction over Actavis because it has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for Actavis Elizabeth LLC and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware (*e.g.*, *Pfizer, Inc. v. Actavis Group HF*, Civil Action No. 1:10-cv-00675 (D. Del.); *Novartis Pharm. Corp v. Actavis, Inc.*, Civil Action No. 1:12-cv-00366 (D. Del.)).

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

THE PATENT-IN-SUIT AND GILENYA®

22. 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.

23. 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.

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

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

INFRINGEMENT BY ACTAVIS OF THE PATENT-IN-SUIT

26. Plaintiffs incorporate each of the preceding paragraphs 1 - 25 as if fully set forth herein.

27. By letters dated November 3, 2014 ("the Notice Letters"), Actavis notified Plaintiffs that Actavis had submitted to the FDA ANDA No. 207972 for Fingolimod Hydrochloride Capsules, Eq. 0.5 mg Base, a drug product that is a generic version of GILENYA® ("Actavis's ANDA Product"). The purpose of Actavis'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 Actavis's ANDA Product prior to the expiration of the '229 patent.

28. In the Notice Letters, Actavis notified Plaintiffs that, as a part of its ANDA, Actavis 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 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's ANDA Product.

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

30. By filing ANDA No. 207972, Actavis has necessarily represented to the FDA that, upon approval, Actavis's ANDA Product will have the same active ingredient, method

of administration, dosage form, and strength as GILENYA®, and will be bioequivalent to GILENYA®.

31. Actavis's submission of ANDA No. 207972 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Actavis'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).

32. Upon information and belief, Actavis had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 207972 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

33. Upon information and belief, Actavis intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Actavis's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207972.

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

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

36. Upon information and belief, Actavis 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.

37. Upon information and belief, Actavis knows that Actavis's ANDA Product is especially made or adapted for use in infringing the '229 patent, and that Actavis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Actavis plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 207972.

38. The foregoing acts by Actavis 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.

39. Upon information and belief, Actavis 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.

40. If Actavis'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 Actavis's submission of ANDA No. 207972, and that Actavis's making, using, offering to sell, or selling in the United States, or importing into the United States of Actavis'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. 207972 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 Actavis, 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 Actavis'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 Actavis engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Actavis'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: December 16, 2014

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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