IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION

CASE NO. _____

NOVARTIS AG,
NOVARTIS PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA CORPORATION, and
MITSUI SUGAR CO., LTD.,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

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. 207993 filed by Apotex 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 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, Tokyo, Japan.

6. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1 T9.

7. Upon information and belief, Apotex Inc. itself, and through its wholly owned subsidiary and agent, Apotex Corp., 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 Apotex Corp. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

9. Upon information and belief, Apotex Corp. 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, Apotex Corp. is a wholly owned subsidiary of Apotex Inc. and is controlled and/or dominated by Apotex Inc. Upon information and belief, Apotex Corp. 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 Apotex Inc. Upon information and belief, Apotex Inc. established Apotex Corp. 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, and Apotex Inc. and Apotex Corp. acted collaboratively in the preparation and submission of ANDA No. 207993.

11. In its letters dated September 14, 2015, ("the Notice Letters"), Apotex notified Plaintiffs that Apotex had submitted to the FDA ANDA No. 207993 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA®. The Notice Letters identify Kiran Krishnan, VP, US Regulatory Affairs of Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326, as the name and address of the agent in the United States authorized to accept service of process for Apotex Inc.

12. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207993, Apotex Inc. and Apotex Corp. 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. 207993 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

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

14. Apotex Inc. and Apotex Corp. are collectively referred to hereafter as "Apotex," unless otherwise noted.

JURISDICTION AND VENUE

15. 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).

16. This Court has personal jurisdiction over Apotex Corp. because, among other things, Apotex Corp. has a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. The Notice Letters also identify Kiran Krishnan, VP, US Regulatory Affairs of Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326, as the name and address of the agent in the United States authorized to accept service of process for Apotex Inc.

17. This Court has personal jurisdiction over Apotex Inc. because, among other reasons: (1) it has extensive contacts with the State of Florida, including through its subsidiary Defendant Apotex Corp; and (2) regularly does business in this district, including through its subsidiary Defendant Apotex Corp. The Notice Letters identify Kiran Krishnan, VP, US Regulatory Affairs of Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326, as the name and address of the agent in the United States authorized to accept service of process for Apotex Inc.

18. This Court also has personal jurisdiction over Apotex because its affiliations with the State of Florida, including by virtue of maintaining a principal place of business of Apotex Corp. in Florida, are so continuous and systematic as to render it essentially at home in this forum. Upon information and belief, Apotex derives substantial revenue from the sale of those products

in Florida and have availed themselves of the privilege of conducting business within the State of Florida.

19. This Court also has personal jurisdiction over Apotex because it has availed itself of the legal protections of the State of Florida by, among other things, selecting the State of Florida as the principal place of business for Apotex Corp. and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the Southern District of Florida (*e.g.*, *Apotex, Inc. et al v. Mylan Pharmaceuticals, Inc.,* Case No. 12-cv-60704 (S.D. Fla., Apr. 20, 2012). Further, Apotex previously admitted that this Court has personal jurisdiction over both Apotex Corp. and Apotex Inc. *See Alcon v. Apotex Inc. & Apotex Corp.*, C.A. No. 1:06-cv-01642, D.E. 23 at 7 (S.D. Ind. Dec. 13, 2006) ("Plaintiffs could have brought this action in the S.D. Fla. because the S.D. Fla. has personal jurisdiction over both Defendants. Apotex Corp. has a principal place of business in Weston, Florida, while Apotex Inc. is a Canadian corporation that regularly conducts business in Florida. Thus, venue in the S.D. Fla. would also be proper.").

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

THE PATENT-IN-SUIT AND GILENYA®

21. 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.

22. 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.

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

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

INFRINGEMENT BY APOTEX OF THE PATENT-IN-SUIT

25. Plaintiffs incorporate each of the proceeding paragraphs 1 - 24 as if fully set forth herein.

26. By the Notice Letters, Apotex notified Plaintiffs that Apotex had submitted to the FDA ANDA No. 207993 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Apotex's ANDA Product"). The purpose of Apotex'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 Apotex's ANDA Product prior to the expiration of the '229 patent.

27. In the Notice Letters, Apotex notified Plaintiffs that, as a part of its ANDA, Apotex 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 Apotex's ANDA Product.

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

29. By filing ANDA No. 207993, Apotex has necessarily represented to the FDA that, upon approval, Apotex's ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as GILENYA®, and will be bioequivalent to GILENYA®.

30. Apotex's submission of ANDA No. 207993 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Apotex'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).

31. Upon information and belief, Apotex had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 207993 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

32. Upon information and belief, Apotex intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207993.

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

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

35. Upon information and belief, Apotex 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.

36. Upon information and belief, Apotex knows that Apotex's ANDA Product is especially made or adapted for use in infringing the '229 patent, and that Apotex's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 207993.

37. The foregoing acts by Apotex 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.

38. Upon information and belief, Apotex 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.

39. If Apotex'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 Apotex's submission of ANDA No. 207993, and that Apotex's making,

using, offering to sell, or selling in the United States, or importing into the United States of Apotex'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. 207993 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 Apotex, 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 Apotex'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 Apotex engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Apotex'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: October 28, 2015

Respectfully submitted,

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