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. HEC PHARM CO., LTD., HEC PHARM GROUP, and HEC PHARM USA INC. 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. 207939 filed by HEC Pharm Co., Ltd. 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").

RELATED ACTION

2. Plaintiffs have filed another patent infringement action currently pending before the Court involving the '229 patent, captioned *Novartis AG, et al. v. Actavis, Inc. et al.*, C.A. No. 1:14-cv-01487-LPS (D. Del.).

PARTIES

3. 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.

4. 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.

5. 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.

6. 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.

7. Upon information and belief, HEC Pharm Group ("HEC Group"), is a company organized and existing under the laws of China, having its principal place of business at Dong Yang Guang Park, Shangsha, Chang'an, Dongguan, Guangdong, 523871, China. Upon information and belief, HEC Group is in the business of developing, manufacturing, marketing, and selling generic drugs. Upon information and belief, HEC Group established Defendants

HEC Pharm Co., Ltd. and HEC Pharm USA Inc. for the purpose of manufacturing, distributing, marketing, and selling its generic drug products throughout the United States.

8. Upon information and belief, HEC Pharm Co., Ltd. ("HEC Ltd.") is a company organized and existing under the laws of China, having its principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China. Upon information and belief, HEC Ltd. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States.

9. Upon information and belief, based in part on representations on their website at URL www.hecpharm.com, HEC Group and HEC Ltd. hold themselves out as a unitary entity. Upon information and belief, HEC Group and HEC Ltd., themselves and through their U.S. agent, Defendant HEC Pharm USA Inc., manufacture and/or distribute generic drugs for sale and use throughout the United States.

10. Upon information and belief, HEC Pharm USA Inc. ("HEC USA") is a company organized and existing under the laws of New Jersey, having its principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540. Upon information and belief, HEC USA is the U.S. agent of HEC Group and HEC Ltd., wherein following FDA approval of an ANDA, HEC Ltd. manufactures and supplies the approved generic product to HEC USA, which then markets and sells the product throughout the United States at the direction, under the control, and for the direct benefit of HEC Ltd. and HEC Group.

11. Upon information and belief, HEC Ltd.'s preparation and submission of ANDA No. 207939 was done at the direction, under the control, and for the direct benefit of HEC Group.

12. Upon information and belief, following any FDA approval of ANDA No. 207939, HEC Ltd. itself and through its U.S. agent, HEC USA, will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207939 throughout the United States, and/or import such generic drug products into the United States.

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

14. HEC Ltd., HEC Group, and HEC USA are collectively referred to hereafter as "HEC."

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 HEC 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. 207939 that has led to foreseeable harm and injury to NPC, a Delaware corporation.

17. This Court also has personal jurisdiction over HEC because its activities (*e.g.*, filing ANDA No. 207939 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 HEC's actions were (and will be) suffered in Delaware.

18. This Court also has personal jurisdiction over HEC because this suit arises out of and relates to HEC's activities that are, and will be, directed to Delaware. This suit arises

from HEC's ANDA filing, which is a prerequisite to obtaining FDA approval, which in turn is necessary in order for HEC to sell its ANDA product in Delaware.

19. This Court also has personal jurisdiction over HEC because at the time HEC sent notice of a paragraph IV certification, it was reasonably foreseeable that HEC would be sued within 45 days in this District, where NPC is organized and where related ANDA litigation had already been filed.

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 HEC.

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 HEC OF THE PATENT-IN-SUIT

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

26. By letters dated January 19, 2015 ("the Notice Letters"), HEC notified Plaintiffs that HEC had submitted to the FDA ANDA No. 207939 for Fingolimod Hydrochloride Capsules, Eq. 0.5 mg Base, a drug product that is a generic version of GILENYA® ("HEC's ANDA Product"). The purpose of HEC'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 HEC's ANDA Product prior to the expiration of the '229 patent.

27. In the Notice Letters, HEC notified Plaintiffs that, as a part of its ANDA, HEC 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 HEC'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. 207939, HEC has necessarily represented to the FDA that, upon approval, HEC'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. HEC's submission of ANDA No. 207939 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of HEC'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, HEC had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 207939 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, HEC intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of HEC's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207939.

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

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

35. Upon information and belief, HEC 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, HEC knows that HEC's ANDA Product is especially made or adapted for use in infringing the '229 patent, and that HEC's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, HEC plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 207939.

37. The foregoing acts by HEC 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, HEC 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 HEC'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, Plaintiffs pray 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 HEC's submission of ANDA No. 207939, and that HEC's making, using, offering to sell, or selling in the United States, or importing into the United States of HEC'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. 207939 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 Plaintiffs is or becomes entitled.

3. An order permanently enjoining HEC, 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 HEC's ANDA Product, until after the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs is or becomes entitled.

4. Damages or other monetary relief to Plaintiffs if HEC engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of HEC's ANDA Product, prior to the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs 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: February 11, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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