**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NOVARTIS PHARMACEUTICALS CORPORATION,<br>Plaintiff,<br><br>v.<br><br>HEC PHARM CO., LTD. and HEC PHARM USA INC.,<br>Defendants. | C.A. No. __ |

## COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff") by its attorneys hereby alleges 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 an Abbreviated New Drug Application ("ANDA") No. 207939 filed by the above-named defendants with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, offer for sale, or sale of a generic version of Novartis's GILENYA® Capsules, 0.5 mg fingolimod, prior to expiration of U.S. Patent No. 10,543,179 ("the '179 patent").

## PARTIES

### A. Plaintiff

2. Novartis Pharmaceuticals Corporation 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.

3. Novartis is in the business of creating, developing, and bringing to market new drug therapies to benefit patients against serious diseases, including treatments for multiple sclerosis. GILENYA® is one such treatment. Novartis markets and sells GILENYA® in this judicial district and throughout the United States.

**B. Defendants**

4. Upon information and belief, Defendant HEC Pharm Co., Ltd. is a corporation organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China.

5. Upon information and belief, Defendant HEC Pharm USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

6. HEC Pharm Co., Ltd. and HEC Pharm USA Inc. are collectively referred to hereafter as "HEC" unless otherwise noted.

7. By a letter dated September 14, 2021, HEC notified Novartis that HEC had submitted to the FDA ANDA No. 207939 for Fingolimod 0.5 mg capsules, a generic version of GILENYA® ("HEC's ANDA Product"), seeking 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 '179 patent.

8. In its Notice Letter, HEC notified Plaintiff 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 '179 patent asserting that the '179 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale of HEC's ANDA Product.

9. Upon information and belief, and consistent with their past practices HEC Pharm Co., Ltd. and HEC Pharm USA Inc. acted collaboratively in the preparation and submission of ANDA No. 207939.

10. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207939, HEC Pharm Co., Ltd. and HEC Pharm USA 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. 207939 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

## JURISDICTION AND VENUE

11. 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).

12. HEC has committed an act of infringement of the ’179 patent in this judicial district by filing ANDA No. 207939 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207939 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

13. HEC has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product

described in ANDA No. 207939 upon approval. Furthermore, upon information and belief, HEC has a regular and established place of business in this judicial district.

14. HEC has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Bristol-Myers Squibb Co. et al. v. Sunshine Lake Pharma Co., Ltd. et al.*, C.A. No. 17-00380 (D. Del.); *Astrazeneca LP et al. v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-1041 (D. Del.). In particular, HEC has filed counterclaims and actively litigated two other patent cases related to GILENYA® in this District. *See Novartis AG et al v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-00151-LPS (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). HEC also has admitted jurisdiction and filed counterclaims, and is actively litigating the most recent GILENYA® case (relating to the same '179 patent) in this District. *Novartis Pharms. Corp. v. Apotex Inc., et al.*, C.A. No. 20-00133-LPS (D. Del.).

15. 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.

**PRIOR GILENYA® LITIGATION WITH HEC**

16. By a letter dated January 28, 2016, HEC notified Plaintiff that HEC had submitted to the FDA the same ANDA No. 207939 for HEC's ANDA Product, seeking approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of HEC's ANDA Product prior to the expiration of U.S. Patent No. 9,187,405 ("the '405 patent").

17. The '405 patent is wholly owned by Novartis.

18. The '405 patent expires on June 25, 2027, and has been granted a six month pediatric regulatory extension to December 25, 2027.

19. Following the receipt of HEC's January 28, 2016 letter, Novartis initiated suits for infringement of the '405 patent against HEC and other generics that were consolidated in this District. *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

20. On December 4, 2019, the FDA granted final approval of HEC's ANDA No. 207939.

21. On September 11, 2020, the Court in *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.) entered an Order, Final Judgement, and Injunction, finding in favor of Novartis and against HEC on Novartis's claims of infringement of claims 1–6 of the '405 patent by HEC's ANDA No. 207939 and on HEC's defenses and counterclaims. The Court permanently enjoined HEC from engaging in the manufacture, use, offer for sale, and/or sale in the United States and/or importation into the United States of HEC's ANDA Product prior to the expiration of the '405 patent.

22. On May 25, 2021, the FDA converted the final approval of HEC's ANDA No. 207939 to a tentative approval.

## THE PATENT-IN-SUIT AND GILENYA®

23. On January 28, 2020, the U.S. Patent and Trademark Office duly and legally issued the '179 patent, entitled "Dosage Regimen of an S1P Receptor Modulator." A true and correct copy of the '179 patent is attached hereto as Exhibit A.

24. The claims of the '179 patent are valid and enforceable. The '179 patent is wholly owned by Novartis, who therefore has the right to sue for and obtain equitable relief and damages for infringement of the '179 patent.

25. Novartis 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.

26. GILENYA® and the use of GILENYA® is covered by one or more claims of the '179 patent.

27. The FDA's official publication of approved drugs (the "Orange Book") lists the '179 patent in connection with GILENYA®.

28. The '179 patent will expire on December 25, 2027.

29. On January 28, 2020, Novartis initiated a suit against HEC in this District, alleging that HEC's submission of ANDA No. 207939 seeking for approval to engage in the commercial manufacture, use, offer for sale, and/or sale of HEC's ANDA Product prior to the expiration of the '179 patent constitutes infringement of one or more claims of the '179 patent. *Novartis Pharms. Corp. v. Apotex Inc., et al.*, C.A. No. 20-00133-LPS (D. Del.). On August 2, 2021, the Court entered a scheduling order setting the case for trial in April 2023. *Id.*, D.I. 97.

30. Following the FDA's conversion of the final approval of HEC's ANDA No. 207939 to a tentative approval, HEC sent its September 14, 2021 Notice Letter with respect to the '179 patent to Novartis.

**INFRINGEMENT BY HEC OF THE PATENT-IN-SUIT**

31. Novartis incorporates each of the proceeding paragraphs 1 - 30 as if fully set forth herein.

32. By filing its ANDA, 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®.

33. 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 '179 patent constitutes infringement of one or more of the claims of the '179 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, HEC had actual and constructive knowledge of the '179 patent at least by January 28, 2020 and has since been aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '179 patent.

35. 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.

36. 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 '179 patent.

37. 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 '179 patent.

38. Upon information and belief, HEC plans and intends to, and will, actively induce infringement of the '179 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. The foregoing acts by HEC constitute and/or will constitute infringement of the '179 patent and/or active inducement of infringement of the '179 patent.

40. Upon information and belief, HEC acted without a reasonable basis for believing that it would not be liable for infringing the '179 patent and/or active inducement of infringement of the '179 patent.

41. If HEC's infringement of the '179 patent is not permanently enjoined, Novartis 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:

A. A judgment that one or more claims of the '179 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 '179 patent.

B. 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 '179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

C. 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 '179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

D. Damages or other monetary relief to Novartis 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 '179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: October 27, 2021

McCARTER & ENGLISH, LLP

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