IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HEC PHARM CO., LTD., HEC PHARM USA INC., SUNSHINE LAKE PHARMA CO., LTD., CANDA HEC-1, LLC, and RISING PHARMA HOLDINGS, INC. D/B/A/ RISING PHARMACEUTICALS, INC., Defendants.	C.A. No. __ **DEMAND FOR JURY TRIAL**

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 the infringement of U.S. Patent No. 10,543,179 ("the '179 patent") by the above-named defendants through their manufacture, use, offer for sale, and sale of a generic version of Novartis's GILENYA® Capsules, 0.5 mg fingolimod within the United States.

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. Upon information and belief, Defendant Sunshine Lake Pharma Co., Ltd. ("Sunshine Lake") is a corporation organized and existing under the laws of China, having a principal place of business at Northern Industry Road 1#, Song Shan Lake, Dongguan 523808, Guangdong, China.

7. Upon information and belief, Sunshine Lake is a subsidiary of HEC Pharm Co., Ltd.

8. HEC Pharm Co., Ltd., HEC Pharm USA Inc., and Sunshine Lake Pharma Co., Ltd. are collectively referred to hereafter as "HEC" unless otherwise noted.

9. By letters dated January 28, 2016 and September 14, 2021, HEC notified Plaintiff that HEC had submitted to the FDA ANDA No. 207939 for fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("HEC's ANDA Product").

10. 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.

11. On the basis of those letters, which signaled HEC's intent to market HEC's ANDA Product prior to the expiration of Novartis patents, including the '179 patent, Novartis has filed several pending actions in this District against HEC. *See Novartis AG et al v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-151-LPS (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.); *Novartis Pharms. Corp. v. Apotex Inc., et al.*, C.A. No. 20-133-GBW (D. Del.); *Novartis Pharms. Corp. v. HEC Pharm Co., Ltd., et al.*, C.A. No. 21-1530-GBW (D. Del.).

12. Upon information and belief, on or about November 10, 2021, HEC obtained final approval from FDA to market, sell, offer for sale, and distribute HEC's ANDA Product in the United States, including in this District.

13. Upon information and belief, Sunshine Lake is responsible for the manufacture of HEC's ANDA Product and has manufactured HEC's ANDA Product for the purpose of importing, marketing, selling, offering for sale, and distributing that product in the United States.

14. Upon information and belief, Defendant CANDA HEC-1, LLC ("CANDA") is a limited liability company organized and existing under the laws of the State of Texas, having a principal place of business at 1404 South New Road, Waco, Texas 76711.

15. Upon information and belief, Defendant Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals, Inc. ("Rising") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3 Pearl Court, Allendale, New Jersey 07401.

16. Upon information and belief, HEC, CANDA, and Rising have entered contractual relationships to market, sell, offer for sale, and distribute HEC's ANDA Product in the United States, including in this District.

17. Upon information and belief, beginning on or about October 17, 2022, HEC, CANDA, and Rising have acted in concert to market, sell, offer for sale, and distribute HEC's ANDA Product in the United States, including in this District.

JURISDICTION AND VENUE

18. 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).

19. Defendants have committed acts of infringement of the '179 patent in this judicial district by making, using, offering to sell, and/or selling the generic drug products that are the subject of ANDA No. 207939, acts of infringement that have caused foreseeable harm and injury to Novartis, a Delaware corporation.

20. Defendants have extensive contacts with the State of Delaware, regularly conduct business in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed itself of the privilege of doing business in the State of Delaware, and sell in the State of Delaware the product described in ANDA No. 207939. Furthermore, upon information and belief, HEC has a regular and established place of business in this judicial district.

21. Rising is a Delaware corporation and is thus "at home" in this District.

22. 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. 17-380 (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. 15-151-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. 20-133-GBW (D. Del.); *Novartis Pharms. Corp. v. HEC Pharm Co., Ltd., et al.*, C.A. No. 21-1530-GBW (D. Del.).

23. CANDA has availed itself of the legal protections of the State of Delaware by, among other things, contractually controlling and benefitting from the litigation HEC has prosecuted in this District, including in *Novartis AG et al v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-151-LPS (D. Del.), *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No.

18-1043-KAJ (D. Del.), *Novartis Pharms. Corp. v. Apotex Inc., et al.*, C.A. No. 20-133-GBW (D. Del.), and *Novartis Pharms. Corp. v. HEC Pharm Co., Ltd., et al.*, C.A. No. 21-1530-GBW (D. Del.).

24. In the related case *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.), HEC and CANDA are actively seeking monetary relief against Novartis in this District.

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

THE PATENT-IN-SUIT AND GILENYA®

26. 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.

27. 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.

28. 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.

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

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

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

PRIOR GILENYA® LITIGATION

32. 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-GBW (D. Del.).

33. 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. Novartis subsequently initiated an additional suit alleging infringement on that basis. *Novartis Pharms. Corp. v. HEC Pharm Co. Ltd, et al.*, C.A. No. 21-cv-01530-GBW (D. Del.).

34. On November 4, 2022, the Court entered a scheduling order setting the aforementioned cases for trial in July 2023. 20-cv-00133-GBW, D.I. 229.

INFRINGEMENT BY DEFENDANTS OF THE PATENT-IN-UNDER 35 U.S.C. § 271(B)

35. Novartis incorporates each of the proceeding paragraphs 1 - 34 as if fully set forth herein.

36. Upon information and belief, Defendants had actual and constructive knowledge of the '179 patent at least by January 28, 2020 and have since been aware that

importing, marketing, selling, offering for sale, and/or distributing HEC's ANDA Product constitutes infringement of the '179 patent.

37. Claim 1 of the '179 patent is reproduced below:

> 1. A method for treating relapsing remitting multiple sclerosis in a patient in need thereof, the method comprising:
>
> (a) identifying a patient at risk of contracting infection caused by varicella zoster virus by testing said patient for a history of infection caused by varicella zoster virus,
>
> (b) vaccinating the patient at risk of contracting infection caused by varicella zoster virus, and
>
> (c) administering orally fingolimod or a pharmaceutically acceptable salt thereof to said patient at a daily dosage of 0.5 mg,
>
> thereby limiting the risk of infection caused by varicella zoster virus.

38. On information and belief, on or about October 17, 2022, Defendants began importing, marketing, selling, offering for sale, and/or distributing HEC's ANDA Product in the United States, including in this District.

39. Upon information and belief, HEC, CANDA, and Rising have already sold and distributed to customers in the United States more than 1,000 prescriptions for HEC's ANDA Product.

40. Upon information and belief, the majority of these sales of HEC's ANDA Product have been sold and distributed to customers who were previously prescribed Novartis's GILENYA®, causing Novartis direct competitive harm.

41. Upon information and belief, Defendants import, market, sell, offer for sale, and distribute HEC's ANDA Product accompanied by the label attached hereto as **Exhibit B (**Defendants' Labeling), which is accessible at https://www.accessdata.fda.gov/spl/data/edbad756-2ade-b95f-e053-2a95a90ae698/edbad756-2ade-b95f-e053-2a95a90ae698.xml.

42. Defendants' Labeling indicates that HEC's ANDA Product has the same active pharmaceutical ingredient – fingolimod hydrochloride – as GILENYA® and has the same dosage, indication, and efficacy as GILENYA®.

43. Defendants' Labeling indicates that HEC's ANDA Product is "indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease[.]"

44. Defendants' Labeling instructs healthcare providers to administer a 0.5 mg fingolimod orally once-daily. (*See* Exhibit B at "DOSAGE AND ADMINISTRATION.")

45. Defendants Labeling, under the heading "WARNINGS AND PRECAUTIONS" and further under the heading "Infections," instructs healthcare providers that "[p]atients without a healthcare professional confirmed history of chickenpox or without documentation of a full course of vaccination against VZV should be tested for antibodies to VZV before initiating fingolimod" and furthermore that "VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with fingolimod."

46. Use of HEC's ANDA Product in accordance with and as directed by Defendants' Labeling for that product infringes at least claim 1 of the '179 patent.

47. Upon information and belief, Defendants intend that others will infringe at least claim 1 of the ’179 patent in accordance with and as directed by Defendants’ Labeling for HEC’s ANDA Product.

48. Upon information and belief, recipients of Defendants’ Labeling have followed the instructions therein.

49. Upon information and belief, and in accordance with the instructions in Defendants’ Labeling, recipients of Defendants’ Labeling have, for the purpose of treating relapsing remitting multiple sclerosis in a patient in need thereof, identified a patient at risk of contracting infection caused by varicella zoster virus by testing said patient for a history of infection caused by varicella zoster virus, vaccinated the patient at risk of contracting infection caused by varicella zoster virus, and administered orally fingolimod or a pharmaceutically acceptable salt thereof to said patient at a daily dosage of 0.5 mg, thereby limiting the risk of infection caused by varicella zoster virus.

50. Upon information and belief, Defendants are aware that recipients of Defendants’ Labeling have followed the instructions therein.

51. Upon information and belief, Defendants, by expressly instructing recipients of Defendants’ Labeling to infringe at least claim 1 of the ’179 patent, intend that recipients of Defendants’ Labeling will infringe at least claim 1 of the ’179 patent.

52. The foregoing acts by Defendants constitute induced infringement of at least claim 1 of the ’179 patent under 35 U.S.C. § 271(b).

53. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for inducing infringement of the ’179 patent.

54. If Defendants' 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:

1. A judgment that one or more claims of the '179 patent is not invalid, is enforceable, and is infringed by Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States, of HEC's ANDA Product.

2. Damages or other monetary relief to Novartis to compensate Novartis for its lost profits, but in no circumstance less than the value of a reasonable royalty, for Defendants' 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.

3. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their 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.

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

Dated: January 11, 2023

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
T: (302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Paul E. Torchia
Sung Bin Lee
Emil Nachman
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000
JLove@gibsondunn.com
RTrenchard@gibsondunn.com
PTorchia@gibsondunn.com
SLee3@gibsondunn.com
ENachman@gibsondunn.com

Anne Y. Brody
Andrew P. Blythe
GIBSON, DUNN & CRUTCHER LLP
3161 Michelson Drive
Irvine, CA 92612
(949) 451-3800
Abrody@gibsondunn.com
ABlythe@gibsondunn.com