IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMA GLOBAL FZE Defendants.	C.A. No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis") 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 Abbreviated New Drug Application ("ANDA") No. 208014 filed by Sun Pharmaceutical Industries, Ltd. 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. 9,187,405 ("the '405 patent").

PARTIES

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. Upon information and belief, Defendant Sun Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

4. Upon information and belief, Sun Pharmaceutical Industries, Ltd. itself, and through its wholly owned subsidiaries and agents, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

5. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

6. Upon information and belief, Defendant Sun Pharma Global FZE is a corporation organized and existing under the laws of Sharjah, United Arab Emirates, having a principal place of business at DMCC Branch 704, Jumeirah Business Center 1, Cluster G, JLT, P.O. Box # 643561, Dubai, United Arab Emirates.

7. Upon information and belief, Sun Pharmaceutical Industries, Ltd. 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, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE are wholly owned subsidiaries of

Sun Pharmaceutical Industries, Ltd. and are controlled and/or dominated by Sun Pharmaceutical Industries, Ltd. Upon information and belief, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE develop, manufacture and/or distribute 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 Sun Pharmaceutical Industries, Ltd. Upon information and belief, Sun Pharmaceutical Industries, Ltd. established Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

8. Upon information and belief, and consistent with their past practices, Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE acted collaboratively in the preparation and submission of ANDA No. 208014.

9. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 208014, Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE 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. 208014 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

10. Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE are collectively referred to hereafter as "Sun" unless otherwise noted.

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. This Court has personal jurisdiction over Sun 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. 208014 that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

13. This Court also has personal jurisdiction over Sun because, among other reasons, it 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, including through its wholly owned subsidiary AR Holding Company, Inc., a corporation registered in the State of Delaware (File Number 4020865), located at 1105 N Market St. Ste. 1300, Wilmington, DE 19801, 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. 208014 upon approval.

14. On information and belief, Sun Pharmaceutical Industries, Inc. is licensed to sell pharmaceutical products in the State of Delaware. Moreover, on information and belief, Sun Pharmaceuticals, Inc. was registered to do business in Delaware (File Number 5615437) and had appointed a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801) for the receipt of service of process.

15. This Court also has personal jurisdiction over Sun because it 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.*, *Pharmacyclics LLC et al. v. Shilpa Medicare Ltd et al.*, C.A. No. 18-237 (D. Del.); *Pfizer Inc. et al. v. Sun Pharmaceutical Industries, Ltd. et al.*, C.A. No. 17-1597 (D. Del.); *Wyeth LLC et al. v. Sun Pharmaceutical Industries, Ltd.*, C.A. No. 17-1362 (D. Del.); *Biogen MA Inc., v. Sun Pharma Global FZE*, C.A. No. 17-848 (D. Del.).

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

17. Venue is proper in this Court under 28 U.S.C. § 1400(b) because, among other things, Sun has committed an act of infringement in this judicial district by filing ANDA No. 208014 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208014 in this judicial district. Furthermore, on information and belief, Sun has a regular and established place of business in this judicial district, including at least through its wholly-owned subsidiary AR Holding Company, Inc.

18. Sun Pharmaceutical Industries, Ltd. and Sun Pharma Global FZE are foreign corporations not residing in any United States judicial district and may therefore be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

19. For these reasons, and for other reasons that will be presented to the Court if venue is challenged, the Court has venue over this action.

THE PATENT-IN-SUIT AND GILENYA®

20. On November 17, 2015, the U.S. Patent and Trademark Office duly and legally issued the ’405 patent, entitled “S1P Receptor Modulators for Treating Relasping[*sic*]-Remitting Multiple Sclerosis.” A true and correct copy of the ’405 patent is attached hereto as **Exhibit A**.

21. Sun petitioned for an *inter partes* review of the `405 patent in IPR 2017-01929 and was joined as a Petitioner to IPR2017-00854.

22. The claims of the ’405 patent are valid and enforceable, as recently held by the United States Patent and Trademark Office in its Final Written Decision following *inter partes* review. *See* **Exhibit B** (IPR2018-00854, Paper 109). The ’405 patent is wholly owned by Novartis, who therefore has the right to sue for and obtain equitable relief and damages for infringement of the ’405 patent.

23. 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.

24. GILENYA® and the use of GILENYA® is covered by one or more claims of the ’405 patent.

25. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’405 patent in connection with GILENYA®.

INFRINGEMENT BY SUN OF THE PATENT-IN-SUIT

26. Plaintiff incorporates each of the proceeding paragraphs 1 - 25 as if fully set forth herein.

27. By a letter dated June 3, 2016, (“the Notice Letter”), Sun notified Plaintiffs that Sun had submitted to the FDA ANDA No. 208014 for Fingolimod 0.5 mg

capsules, a drug product that is a generic version of GILENYA® ("Sun's ANDA Product"). The purpose of Sun'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 Sun's ANDA Product prior to the expiration of the '405 patent.

28. In the Notice Letter, Sun notified Plaintiff that, as a part of its ANDA, Sun 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 '405 patent asserting that the '405 is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Sun's ANDA Product.

29. By filing ANDA No. 208014, Sun has necessarily represented to the FDA that, upon approval, Sun's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®.

30. Sun's submission of ANDA No. 208014 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Sun's ANDA Product, prior to the expiration of the '405 patent constitutes infringement of one or more of the claims of the '405 patent under 35 U.S.C. § 271(e)(2)(A).

31. Upon information and belief, Sun intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Sun's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208014.

32. Upon information and belief, the Sun ANDA Product proposed labeling will be substantially identical to the GILENYA® label, and the GILENYA® label discloses all

elements of at least claim 1 of the `405 patent. Thus, upon information and belief, the Sun ANDA Product labeling will disclose all elements of at least claim 1 of the ’405 patent.

33. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Sun’s ANDA Product would infringe one or more claims of the ’405 patent.

34. Upon information and belief, use of Sun’s ANDA Product in accordance with and as directed by Sun’s proposed labeling for that product would infringe one or more claims of the ’405 patent.

35. Upon information and belief, Sun plans and intends to, and will, actively induce infringement of the ’405 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, Sun knows that Sun’s ANDA Product is especially made or adapted for use in infringing the ’405 patent, and that Sun’s ANDA Product is not suitable for any substantial noninfringing use. Upon information and belief, Sun plans and intends to, and will, contribute to the infringement of the ’405 patent immediately and imminently upon approval of ANDA No. 208014.

37. The foregoing acts by Sun constitute and/or will constitute infringement of the ’405 patent, active inducement of infringement of the ’405 patent, and/or contribution to the infringement by others of the ’405 patent under 35 U.S.C. §§ 271(a)–(c).

38. Upon information and belief, Sun acted without a reasonable basis for believing that it would not be liable for infringing the ’405 patent, active inducement of infringement of the ’405 patent, and/or contribution to the infringement by others of the ’405 patent.

39. If Sun's infringement of the '405 patent is not enjoined, Plaintiff 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 '405 patent is not invalid, is enforceable, and is infringed by Sun's submission of ANDA No. 208014, and that Sun's making, using, offering to sell, or selling in the United States, or importing into the United States of Sun's ANDA Product will infringe the '405 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. 208014 shall be a date not earlier than the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

3. An order enjoining Sun, 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 Sun's ANDA Product, until after the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. Damages, including monetary or other relief, to Novartis if Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Sun's ANDA Product, prior to the expiration date of the '405 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: July 13, 2018

McCARTER & ENGLISH, LLP

By: /s/ Daniel M. Silver
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Benjamin A. Smyth (#5528)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
bsmyth@mccarter.com

Attorneys Novartis Pharmaceuticals Corporation

OF COUNSEL:

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

Andrew P. Blythe
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071
(213) 229-7000
ABlythe@gibsondunn.com

Attorneys for Novartis Pharmaceuticals Corporation