IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMA GLOBAL FZE, Defendants.	)	C.A. No. 18-cv-1040-LPS

ANSWER, ADDITIONAL DEFENSES, AND COUNTERCLAIMS

Defendants Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), and Sun Pharma Global FZE ("Sun FZE") (collectively, "Sun"), by and through their undersigned attorneys, answer the complaint of Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff"), upon knowledge with respect to Defendants' own acts, and upon information and belief as to other matters, 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").

ANSWER: Paragraph 1 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 1 to the extent they relate to Sun FZE. To the extent a further response is required, Sun admits that the Complaint purports to set forth claims

of patent infringement concerning U.S. Patent No. 9,187,405 ("the '405 patent") related to ANDA No. 208014. Sun Ltd. and Sun Inc. further admit that they submitted ANDA No. 208014 to FDA to obtain approval to engage in the commercial manufacture, use, or sale of Fingolimod 0.5 mg capsules prior to the expiration of the '405 patent. Except as expressly admitted, Sun denies the allegations of Paragraph 1 of the Complaint.

THE 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.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and therefore, Sun denies the allegations in Paragraph 2.

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.

ANSWER: Admitted.

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.

ANSWER: Paragraph 4 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 4 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. admit that they submitted ANDA No. 208014 seeking approval to market the products that are the subject of that application. Although Sun FZE is not a proper party to this action, Sun Ltd. and Sun FZE admit that Sun

FZE is a wholly owned subsidiary of Sun Pharma Holdings, which is a wholly owned subsidiary of Sun Ltd. Sun Ltd. and Sun Inc. further admit that Sun Inc. is a wholly owned subsidiary of Sun Ltd. Except as expressly admitted, Sun denies any remaining allegations in Paragraph 4.

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.

ANSWER: Admitted.

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.

ANSWER: Sun denies that Sun FZE is a proper party to this action. Although Sun FZE is not a proper party to this action, Sun FZE admits that it is a corporation organized and existing under the laws of the United Arab Emirates having a principal place of business at Office # 43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. Except as expressly admitted, Sun denies any remaining allegations in Paragraph 6.

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.

ANSWER: Paragraph 7 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 7 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. admit that they submitted ANDA No. 208014 seeking approval to market the products that are the subject of that application. Although Sun FZE is not a proper party to this action, Sun Ltd. and Sun FZE admit that Sun FZE is a wholly owned subsidiary of Sun Pharma Holdings, which is a wholly owned subsidiary of Sun Ltd. Sun Ltd. and Sun Inc. further admit that Sun Inc. is a wholly owned subsidiary of Sun Ltd. Except as expressly admitted, Sun denies any remaining allegations in Paragraph 7.

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.

ANSWER: Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 8 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. admit that they submitted ANDA No. 208014 seeking approval to market the products that are the subject of that application. Except as expressly admitted, Sun denies any remaining allegations in Paragraph 8.

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.

ANSWER: Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 9 to the extent they relate to Sun FZE. To the extent a response is required, Sun Ltd. and Sun Inc. admit that they submitted ANDA No. 208014 seeking approval to market the products that are the subject of that application. Except as expressly admitted, Sun denies any remaining allegations in Paragraph 9.

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

ANSWER: Paragraph 10 does not contain factual allegations for which a response is required. To the extent a response is required, Sun denies the allegations in Paragraph 10 of the Complaint.

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).

ANSWER: Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 11 to the extent they relate to Sun FZE. To the extent a response is required, Sun admits only that this action purports to arise under the patent laws of the United States and that this Court has subject matter jurisdiction. Sun denies any and all remaining allegations in Paragraph 11 of the Complaint.

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.

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 12 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. do not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 12 of the Complaint.

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.

ANSWER: Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 13 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. do not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 13 of the Complaint.

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 [sic], 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.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 14 to the extent they relate to Sun FZE. To the

extent an answer is required, Sun Inc. admits that it is registered to do business in Delaware as a foreign corporation, with filing number 5615437 and that Sun Inc. has a designated agent in Delaware. Except as expressly admitted, Sun denies the allegations of Paragraph 14. For the purposes of this action only, Sun Ltd. and Sun Inc. do not contest personal jurisdiction in this Court. Sun denies any and all remaining allegations in Paragraph 14 of the Complaint.

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.).

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 15 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. do not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 15 of the Complaint.

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.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 16 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. do not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 16 of the Complaint.

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.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 17 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. do not contest venue for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 17 of the Complaint.

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).

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 18 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. admits that it is a corporation organized and existing under the laws of India and Sun FZE admits that it is a corporation organized and existing under the laws of the United Arab Emirates. To the extent a further response is required, Sun Ltd. and Sun. Inc. do not contest personal jurisdiction or venue in this Court for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 18 of the Complaint.

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.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and

therefore denies the allegations of Paragraph 19 to the extent they relate to Sun FZE. To the extent a further response is required, Sun Ltd. and Sun Inc. do not contest venue for purposes of this action only. Sun denies any and all remaining allegations in Paragraph 19 of the Complaint.

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.

ANSWER: To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 20 to the extent they relate to Sun FZE. To the extent a further response is required, Sun admits that the '405 patent, on its face, is entitled "S1P Receptor Modulators for Treating Relasping[sic]-Remitting Multiple Sclerosis," and states the date of issue as November 17, 2015. Sun further admits that Exhibit A to the Complaint purports to be a copy of the '405 patent. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 20, and therefore denies those allegations.

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.

ANSWER: Admitted.

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.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 22 to the extent they relate to Sun FZE. To the

extent a response is required, Sun admits that Exhibit B purports to be Paper 109 from IPR2017-00854. Sun further admits that the '405 patent, on its face, lists Novartis AG as the assignee. Sun denies that the '405 patent is valid and enforceable. To the extent a further response is required, Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 22, and therefore denies those allegations.

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.

ANSWER: Sun admits that the FDA website lists NDA No. 022527 is held by Novartis Pharmaceuticals Corp. and has been approved by FDA in connection with GILENYA®. Sun further admits that the FDA website states that GILENYA® is indicated for treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 23, and therefore denies those allegations.

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

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 24 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. Sun denies any and all remaining allegations in Paragraph 24 of the Complaint.

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

ANSWER: Admitted based on information available via the FDA's website.

ALLEGED INFRINGEMENT BY SUN OF THE PATENT-IN-SUIT

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

ANSWER: Sun incorporates by reference each of its answers to 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.

ANSWER: Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 27 to the extent they relate to Sun FZE. Sun Ltd. and Sun Inc. admit that the June 3, 2016, Notice Letter notified Plaintiff that Sun Ltd. and Sun Inc. submitted ANDA No. 208014 to the FDA pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii)) and Section 314.95 of the Food and Drug Administration Regulations (21 C.F.R. § 314.95). Sun Ltd. and Sun Inc. further admit they submitted ANDA No. 208014 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 208014. Except as expressly admitted, Sun Ltd., Sun Inc., and Sun FZE deny the allegations of Paragraph 27.

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.

ANSWER: Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 28 to the extent they relate to Sun FZE. Sun Ltd. and Sun Inc. admit that the Notice Letter states that ANDA No. 208014 was submitted with a paragraph IV certification. Sun Ltd. and Sun. Inc. further admit that the Notice Letter states that attached to the Notice Letter is a detailed statement of the factual and legal bases why, in the opinion of Sun Ltd. and Sun Inc., and to the best of Sun Ltd.'s and Sun Inc.'s knowledge, the claims of the '405 patent will not be infringed by the proposed drug product in ANDA No. 208014, the claims are invalid, and/or the claims are unenforceable. Except as expressly admitted, Sun denies the allegations of Paragraph 28.

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®.

ANSWER: Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 29 to the extent they relate to Sun FZE. Sun Ltd. and Sun Inc. admit that they submitted ANDA No. 208014 to the FDA seeking approval to market the product described in ANDA No. 208014. The contents of the ANDA speak for themselves. Except as expressly admitted, Sun denies any remaining allegations in Paragraph 29.

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).

ANSWER: Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 30 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the

’405 patent. To the extent a further response is required, Sun denies the allegations of Paragraph 30.

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.

ANSWER: Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 31 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies the allegations of Paragraph 31.

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.

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 32 to the extent they relate to Sun FZE. To the extent a response is required, Sun Ltd. and Sun Inc. admit that under the Federal Food, Drug, and Cosmetic Act (except in the case of exceptions not available here), an ANDA applicant must “show that the labeling proposed for the new drug is the same as labeling approved for the listed drug.” 21 U.S.C. § 355(j)(2)(A)(v). To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the ’405 patent. Except as expressly admitted, Sun denies the allegations of Paragraph 32.

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.

ANSWER: Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 33 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a further response is required, Sun denies the allegations of Paragraph 33.

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.

ANSWER: Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 34 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a further response is required, Sun denies the allegations of Paragraph 34.

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.

ANSWER: Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 35 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a further response is required, Sun denies the allegations of Paragraph 35.

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.

ANSWER: Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 36 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a further response is required, Sun denies the allegations of Paragraph 36.

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).

ANSWER: Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 37 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a further response is required, Sun denies the allegations of Paragraph 37.

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.

ANSWER: Paragraph 38 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 38 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a response is required, Sun denies the allegations of Paragraph 38.

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.

ANSWER: Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, Sun denies that Sun FZE is a proper party to this action and therefore denies the allegations of Paragraph 39 to the extent they relate to Sun FZE. To the extent a response is required, Sun denies that it infringes any valid and enforceable claim of the '405 patent. To the extent a response is required, Sun denies the allegations of Paragraph 39.

PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint is a prayer for relief, and does not require a response. To the extent any response is required, Sun denies that Plaintiffs are entitled to any remedy or relief.

ADDITIONAL DEFENSES

Sun hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Sun reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

First Additional Defense

The filing of ANDA No. 208014 has not infringed and does not infringe any valid and enforceable claim of the '405 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Additional Defense

The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 208014 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '405 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

Third Additional Defense

The claims of the ’405 patent are invalid and/or unenforceable under one or more provisions of 35 U.S.C. § 100 et seq., such as sections 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidation, such as double patenting.

Fourth Additional Defense

The Complaint fails to state a claim upon which relief can be granted.

Fifth Additional Defense

Sun’s actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Additional Defense

Sun has not willfully infringed any claim of the ’405 patent.

Seventh Additional Defense

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application leading to the ’405 patent, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the ’405 patent is infringed by the products that are the subject of ANDA No. 208014.

Eighth Additional Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiff/Counterclaim-Defendant Novartis Pharmaceuticals Corporation, Defendants/Counterclaim-Plaintiffs, Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") state as follows:

PARTIES

1. Defendant/Counterclaim-Plaintiff Sun 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.

2. Defendant/Counterclaim-Plaintiff Sun 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.

3. Upon information and belief, Plaintiff/Counterclaim-Defendant 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.

JURISDICTION AND VENUE

4. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. These counterclaims arise under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Plaintiff/Counterclaim Defendant because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint here.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1400(a).

8. There is an actual and justiciable controversy between the parties as to the infringement of U.S. Patent No. 9,187,405 ("the '405 patent").

FACTUAL BACKGROUND

A. FDA Approval Of New Brand-Name Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. See 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the Approved Drug Products with Therapeutic Equivalence Evaluations commonly known as the "Orange Book." See 21 C.F.R. § 314.53(e).

13. The FDA's duties with respect to the Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. See 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval Of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. See Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

16. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. See 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV); see also 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. See 21 U.S.C. § 355(j)(2)(B).

19. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. See 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. See 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. ANDA No. 208014

22. Sun Ltd. and Sun Inc. filed ANDA No. 208014 seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of Fingolimod 0.5 mg capsules prior to the expiration of the '405 patent.

23. On information and belief, FDA lists Novartis Pharmaceuticals Corp. as the holder of NDA No. 022527.

24. On information and belief, NDA No. 022527 covers GILENYA® (Fingolimod 0.5 mg) capsules.

25. On information and belief, Plaintiff listed the '405 patent in the Orange Book in connection with NDA No. 022527.

26. ANDA No. 208014 includes a Paragraph IV certification with respect to the '405 patent.

27. On June 3, 2016, Sun Ltd. and Sun Inc. sent a Notice Letter to Plaintiff providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that no valid claim of the ’405 patent is infringed, directly or indirectly, by the commercial manufacture, use, offer for sale, and/or sale of the product described in ANDA No. 208014.

28. The Notice Letter also contained an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow Plaintiff the opportunity to review the relevant portions of ANDA No. 208014.

29. Sun Ltd., Sun Inc., and Sun Pharma Global FZE petitioned for an inter partes review of the ’405 patent in IPR2017-01929, which was joined with IPR2017-00854. The United States Patent and Trademark Office has issued a final written decision, which is being appealed to the Court of Appeals for the Federal Circuit.

30. Plaintiff did not respond to the Notice Letter and has not waited for the resolution of the appeal in the inter partes review, but rather initiated the present litigation by filing a complaint against Sun Ltd., Sun Inc., and Sun Pharma Global FZE on July 13, 2018.

31. Plaintiff has alleged in the present action that Sun Ltd., Sun Inc., and Sun Pharma Global FZE have infringed and will infringe the ’405 patent by filing ANDA No. 208014 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

32. As a consequence of the foregoing, there is an actual and justiciable controversy as to whether the claims of the ’405 patent are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by ANDA No. 208014 or by the manufacture, use, or sale of the products described therein.

COUNT I
(Declaration of Non-Infringement of the ’405 Patent)

33. Sun Ltd. and Sun Inc. re-allege and incorporate the allegations of paragraphs 1-32 as if fully set forth herein.

34. Plaintiff alleges ownership, title, and/or interest to the ’405 patent and has brought claims against Sun Ltd. and Sun Inc. alleging infringement of the ’405 patent.

35. The manufacture, use, or sale of the product described in ANDA No. 208014 would not infringe any valid or enforceable claim of the ’405 patent, either directly or indirectly.

36. On June 3, 2016, Sun Ltd. and Sun Inc. sent a Notice Letter to Plaintiff providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for their opinion that the ’405 patent is not infringed, directly or indirectly, by the commercial manufacture, use, offer for sale, and/or sale of the product described in ANDA No. 208014.

37. A present, genuine, and justiciable controversy exists between Sun Ltd. and Sun Inc., on the one hand, and Plaintiff, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the product described in ANDA No. 208014 would infringe any valid or enforceable claim of the ’405 patent.

38. Sun Ltd. and Sun Inc. are entitled to a declaration that the manufacture, use, or sale of the product described in ANDA No. 208014 would not infringe any valid or enforceable claim of the ’405 patent.

39. This case is an exceptional one, and Sun Ltd. and Sun Inc. are entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Invalidity of the ’405 Patent)

40. Sun Ltd. and Sun Inc. re-allege and incorporate the allegations of paragraphs 1-39

as if fully set forth herein.

41. Plaintiff alleges ownership of the ’405 patent and has brought claims against Sun Ltd. and Sun Inc. alleging infringement of the ’405 patent.

42. One or more of the claims of the ’405 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

43. One or more of the claims of the ’405 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of prior art to the ’405 patent.

44. On June 3, 2016, Sun Ltd. and Sun Inc. sent a Notice Letter to Plaintiff providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for their opinion that the ’405 patent is invalid.

45. A present, genuine, and justiciable controversy exists between Sun Ltd. and Sun Inc., on the one hand, and Plaintiff, on the other, regarding, *inter alia*, the validity of claims of the ’405 patent.

46. Sun Ltd. and Sun Inc. are entitled to a declaration that claims of the ’405 patent are invalid.

47. This case is an exceptional one, and Sun Ltd. and Sun Inc. are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Defendants/Counterclaim-Plaintiffs respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

(a) declaring that Defendants have not infringed any valid and enforceable claim of the U.S. Patent No. 9,187,405;

(b) declaring that the claims of U.S. Patent No. 9,187,405 are invalid;

(c) dismissing the Complaint with prejudice;

(d) declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding Defendants their costs, expenses, and reasonable attorneys' fees in this action;

(e) awarding Defendants the costs of this action; and

(f) awarding Defendants any further and additional relief as the Court deems just and proper.

HEYMAN ENERIO
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