IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Plaintiff,	)	C.A. No. 18-1038-LPS
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

DEFENDANTS APOTEX INC. AND APOTEX CORP.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex"), through their attorneys, hereby submit this Answer, Defenses, and Counterclaims to the Complaint filed by Plaintiff Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff"). D.I. 1 ("Complaint").

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Apotex denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, and not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Apotex denies that Plaintiffs are entitled to the relief requested or any other relief. Apotex responds to the Complaint 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. 207993 filed by Apotex Inc. 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 states legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the Complaint purports to state an action for patent infringement, brought pursuant to the patent laws of the United States, Title 35, United States Code, arising from the submission of Abbreviated New Drug Application ("ANDA") No. 207993 (the "Apotex ANDA") to the United States Food & Drug Administration (the "FDA"). Apotex further admits that the Complaint purports to allege that Apotex seeks approval to market a generic version of GILENYA® Capsules, 0.5 mg, prior to the expiration of U.S. Patent No. 9,187,405 (the "'405 patent"). Apotex denies the remaining allegations of paragraph 1.

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: Apotex admits that publically available documents indicate that Novartis Pharmaceuticals Corporation ("Novartis") is a corporation organized and existing under the laws of the State of Delaware. To the extent not expressly admitted, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 and therefore denies them.

3. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1 T9.

Answer: Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada and that it has an office located at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 3.

4. Upon information and belief, Apotex Inc. itself, and through its wholly-owned subsidiary and agent, Apotex Corp., develops, manufactures and/or distributes generic drug

products for marketing, sale, and/or use throughout the United States, including in this judicial district.

Answer: Apotex admits that Apotex Inc. is in the business of manufacturing, marketing and selling generic drug products. Apotex admits that Apotex Corp. sells drug products within the United States. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 4.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

Answer: Apotex admits that Apotex Corp. is a corporation organized and existing under the laws of Delaware and that it has an office located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 5.

6. Upon information and belief, Apotex Inc. 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, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. and is controlled and/or dominated by Apotex Inc. Upon information and belief, Apotex Corp. develops, manufactures and/or distributes 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 Apotex Inc. Upon information and belief, Apotex Inc. established Apotex Corp. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

Answer: Apotex admits that Apotex Inc. is in the business of manufacturing, marketing and selling generic drug products. Apotex admits that Apotex Corp. sells drug products within the United States. To the extent not expressly admitted, Apotex denies the allegations of paragraph 6.

7. Upon information and belief, and consistent with their past practices, Apotex Inc. and Apotex Corp. acted collaboratively in the preparation and submission of ANDA No. 207993..

Answer: Apotex admits that Apotex Inc. submitted ANDA No. 207993. Apotex denies the remaining allegations.

8. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207993, Apotex Inc. and Apotex Corp. 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. 207993 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

Answer: Apotex admits that Apotex Inc. submitted ANDA No. 207993. Apotex denies the remaining allegations.

9. Apotex Inc. and Apotex Corp. are collectively referred to hereafter as "Apotex," unless otherwise noted.

Answer: Apotex admits that the **Complaint** purports to hereafter refer to Apotex Inc. and Apotex Corp. collectively as "Apotex."

JURISDICTION AND VENUE

10. 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 10 contains conclusions of law for which no response is required. To the extent a response is required, Apotex admits that the Complaint purports to state an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, but denies that Plaintiffs' claims have merit. Apotex does not contest that the Court has subject matter jurisdiction over this action. Apotex does not contest venue for purposes of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 10.

11. This Court has personal jurisdiction over Apotex 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. 207993 that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

Answer: Paragraph 11 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 11.

12. This Court also has personal jurisdiction over Apotex because its affiliations with the State of Delaware, including by virtue of the incorporation of Apotex Corp. in Delaware, are so continuous and systematic as to render it essentially at home in this forum.

Answer: Paragraph 12 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 12.

13. This Court has personal jurisdiction over Apotex Corp. because, among other reasons, it is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this district. On information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy, pursuant to Del. Code tit. 24, § 2540, as a licensed "Pharmacy—Wholesale[r]" (License No. A4-0001921) and "Distributor/Manufacturer CSR" (License No. DM-0008873). Moreover, on information and belief, Apotex Corp. has appointed a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801)) for the receipt of service of process.

Answer: Paragraph 13 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex Corp does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 13.

14. This Court has personal jurisdiction over Apotex Inc. because, among other reasons: (1) it has extensive contacts with the State of Delaware, including through its subsidiary Apotex Corp.; and (2) regularly does business in this district, including through its subsidiary Apotex Corp.

Answer: Paragraph 14 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex Inc. does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 14.

15. This Court also has personal jurisdiction over Apotex because it has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for Apotex Corp. and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Pfizer Inc. et al v. Apotex Inc. et al.*, C.A. No. 18-00795 (D. Del.); *Novartis AG et al v. Apotex Inc. et al.*, C.A. No. 15-00975 (D. Del.); *Otsuka Pharm. Co. v. Apotex Inc. et al*., C.A. No. 15-00109 (D. Del.); *Aptalis Pharmatech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 14-01038 (D. Del.); *Apotex, Inc. et al. v. Senju Pharm. Co., Ltd*., C.A. No. 12-cv-00196 (D. Del.); *Acorda Therapeutics, Inc. v. Apotex Corp*., C.A. No. 14-cv-00955 (D. Del.); *Warner Chilcott Co., LLC v. Apotex, Inc*., C.A. No. 1:14-cv-00998 (D. Del.); *Pfizer Inc. v. Apotex Inc*., C.A. No. 1:13-cv-02022 (D. Del.); *Boehringer Ingelheim Pharms., Inc. v. Apotex Inc. et al.*, C.A. No. 08-00065 (D. Del.).

Answer: Paragraph 15 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 15.

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 Apotex.

Answer: Paragraph 16 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 16.

17. Venue is proper in this Court because, among other things, Apotex Corp. is incorporated in the State of Delaware and therefore "resides" in this judicial district for purposes of 28 U.S.C. § 1400(b). Apotex Inc. is a foreign corporation 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 17 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 17.

THE PATENT-IN-SUIT AND GILENYA®

18. 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: Apotex denies that the claims of the '405 patent are valid and enforceable. Apotex further denies that Plaintiffs' claims have merit. Apotex admits that the '405 patent states on its face that it is entitled "S1P Receptor Modulators for Treating Relasping[*sic*]-Remitting Multiple Sclerosis" and states that it was issued on November 15, 2015. Apotex further admits that Exhibit A purports to be a copy of the '405 patent. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 18.

19. Apotex petitioned for an inter partes review of the '405 patent in IPR2017-00854. 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: Apotex admits that Apotex petitioned for an *inter partes* review of the '405 patent in IPR2017-00854. Apotex admits that the United States Patent and Trademark Office issued a Final Written Decision, identified as Exhibit B. Apotex further admits that the '405 on

its face states Novartis as its sole assignee. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 19.

20. 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: Apotex admits that Novartis Pharmaceutical Corporation is listed in publically available documents as the holder of New Drug Application ("NDA") No. 022527 and that NDA No. 022527 was approved by the FDA. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20 and, therefore, deny the same.

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

Answer: Paragraph 21 contains conclusions of law for which no response is required. To the extent that a response is required, Apotex denies the allegations of paragraph 21.

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

Answer: The public documents referenced in paragraph 22 speak for themselves and are the best evidence of their contents. To the extent that a response is required, Apotex admits that the '405 patent appears to be listed in the online version of the Orange Book for GILENYA®. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 22.

INFRINGEMENT

23. Plaintiffs incorporate each of the proceeding paragraphs 1 - 22 as if fully set forth herein.

Answer: Apotex repeats and incorporates by reference its responses to paragraphs 1-22 of the Complaint.

24. By a letter dated January 22, 2016, ("the Notice Letter"), Apotex notified Plaintiffs that Apotex had submitted to the FDA ANDA No. 207993 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Apotex's ANDA Product"). The purpose of Apotex'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 Apotex's ANDA Product prior to the expiration of the '405 patent.

Answer: Apotex admits that Apotex Inc. by a letter dated January 22, 2016 ("the Notice Letter") notified Plaintiff that it had submitted to the FDA ANDA No. 207993 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA" ("Apotex's ANDA Product"). To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 24.

25. In the Notice Letter, Apotex notified Plaintiff that, as a part of its ANDA, Apotex 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 Apotex's ANDA Product.

Answer: Apotex admits that the Notice Letter stated that the Apotex ANDA contains paragraph IV certifications and asserts that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of the Apotex Product. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 25.

26. By filing ANDA No. 207993, Apotex has necessarily represented to the FDA that, upon approval, Apotex'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: Paragraph 26 contains conclusions of law, for which no response is required. To the extent that a response is required, on information and belief, Apotex admits that Apotex's ANDA product contains the same active ingredients and strength as GILENYA®. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 26.

27. Apotex's submission of ANDA No. 207993 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Apotex'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: Denied.

28. Upon information and belief, Apotex intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207993.

Answer: Denied.

29. Upon information and belief, the Apotex 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 Apotex ANDA Product labeling will disclose all elements of at least claim 1 of the '405 patent.

Answer: Denied.

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

Answer: Denied.

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

Answer: Denied.

32. Upon information and belief, Apotex 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: Denied.

33. Upon information and belief, Apotex knows that Apotex's ANDA Product is especially made or adapted for use in infringing the '405 patent, and that Apotex's ANDA Product is not suitable for any substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to the infringement of the '405 patent immediately and imminently upon approval of ANDA No. 207993.

Answer: Denied.

34. The foregoing acts by Apotex 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: Denied.

35. Upon information and belief, Apotex 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: Denied.

36. If Apotex'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: Denied.

PRAYER FOR RELIEF

Apotex denies that Plaintiffs are entitled to any of the relief they seek in the prayer for relief or any relief whatsoever.

DEFENSES

Further responding to the Complaint, Apotex responds with certain defenses as set forth below. Apotex reserves all defenses, at law or equity, that may now exist or in the future be available on discovery and further factual investigation in this case.

FIRST DEFENSE

The manufacture, use, sale, offer for sale, or importation of the Apotex Product that is the subject of the Apotex ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '405 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

SECOND DEFENSE

Each and every asserted claim of the ’405 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

THIRD DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

COUNTERCLAIMS

Without admitting any of the allegations of Novartis Pharmaceuticals Corporation, (“Counterclaim-Defendant” or “Novartis”), other than those expressly admitted herein, and without prejudice to the rights of Apotex Inc. and Apotex Corp. (collectively, “Counterclaim-Plaintiffs”) to plead additional Counterclaims as the facts of the matter warrant, Counterclaim Plaintiffs hereby assert the following Counterclaims against Counterclaim Defendant.

NATURE OF THE ACTION

These Counterclaims seek a declaratory judgment that the Fingolimod Capsules, 0.5 mg (the “Apotex Product”) described in Apotex’s ANDA No. 207993 (the “Apotex ANDA”) do not infringe any valid and enforceable claim of U.S. Patent No. 9,187,405 (the “’405 patent”), if any, and that each and every claim of the ’405 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and 112.

THE PARTIES

1. Counterclaim-Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1 T9.

2. Counterclaim-Plaintiff Apotex Corp. is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Counterclaim-Defendant Novartis Pharmaceuticals Corporation is a Delaware corporation with an office and place of business at 1 Health Plz, East Hanover, New Jersey 07936.

JURISDICTION AND VENUE

4. This is a counterclaim for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties concerning non-infringement and invalidity of the '405 patent.

8. This Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), the patent laws of the United States set forth at 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. Personal jurisdiction over Counterclaim Defendant is proper because, *inter alia*, Counterclaim Defendant has consented to the personal jurisdiction of this Court by commencing their action for patent infringement in this Judicial District, as set forth in their Complaint, and by incorporating in the state of Delaware.

10. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

11. According to the United States Food & Drug Administration ("FDA") publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") and the Drugs@FDA website, Novartis Pharmaceuticals Corporation holds approved New Drug Application ("NDA") No. 022527 for GILENYA®.

12. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

13. The ’405 patent is entitled on its face S1P Receptor Modulators for Treating Relasping[*sic*]-Remitting Multiple Sclerosis” and states that it was issued on November 17, 2015.

14. Upon information and belief, and as stated in Counterclaim Defendant’s Complaint in this action, the ’405 patent is owned by Novartis Pharmaceuticals Corporation.

15. Upon information and belief, Counterclaim Defendant caused the ’405 patent to be listed in the online version of the Orange Book as a patent that claims GILENYA® or methods of using GILENYA®.

16. FDA ANDA No. 207993 (“Apotex ANDA”) was filed by Apotex Inc. seeking FDA approval to engage in the commercial manufacture, use, or sale of the Apotex Product.

17. The Apotex ANDA contained a “paragraph IV certification” under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’405 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Apotex Product.

18. On July 13, 2018, Counterclaim Defendants filed this lawsuit alleging infringement of the ’405 patent.

COUNT I:
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’405 PATENT

19. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1-18 of these Counterclaims.

20. There is an actual, substantial, confirming, and justiciable controversy between the parties regarding the invalidity of the ’405 patent, based on Counterclaim Defendant’s

allegation in its Complaint that Counterclaim Plaintiffs have infringed or will infringe the ’405 patent.

21. Each and every claim of the ’405 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112.

22. The alleged invention of the ’405 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

23. The alleged invention of the ’405 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

24. The ’405 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

25. The alleged invention of the ’405 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’405 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’405 patent and would have had a reasonable expectation of success in doing so.

26. The subject matter claimed in the ’405 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or

would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

27. Counterclaim Plaintiffs are entitled to a judicial declaration that all claims of the ’405 patent are invalid.

COUNT II:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’405 PATENT

28. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1-27 of these Counterclaims.

29. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the Apotex ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of the Apotex Product infringes, has infringed, or will infringe any valid and enforceable claim of the ’405 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

30. Counterclaim Plaintiffs have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’405 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

31. Counterclaim Plaintiffs are entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the ’405 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Apotex Product that is the subject of the Apotex ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’405 patent.

COUNTERCLAIM PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, Counterclaim Plaintiffs respectfully request that this Court enter judgment in their favor against Counterclaim Defendants and issue an order:

(a) Dismissing the Counterclaim Defendants' Complaint with prejudice and denying each request for relief made by Counterclaim Defendants;

(b) Declaring all claims of the '405 patent invalid;

(c) Declaring that the filing of the Apotex ANDA has not infringed and does not infringe any valid and enforceable claim, if any, of the '405 patent;

(d) Declaring that Apotex has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, of the '405 patent;

(e) Declaring that Apotex has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, of the '405 patent;

(f) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of the Apotex Product does not, and would not, if marketed, directly or indirectly infringe any valid and enforceable claim, if any, of the '405 patent;

(g) Declaring this case is an exceptional case in favor of Counterclaim Plaintiffs pursuant to 35 U.S.C. § 285;

(h) Awarding costs and attorneys' fees to Counterclaim Plaintiffs; and

(i) Awarding Counterclaim Plaintiffs such other and further relief as the Court deems just and equitable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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