IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendant.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") for their Complaint against Defendants Apotex Inc. and Apotex Corp. (together, "Apotex") allege as follows:

THE PARTIES

1. Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico. AML manufactures and sells biologic medicines for treating particular diseases in humans.

3. On information and belief, Apotex Inc. is a corporation existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Upon information and belief, acting in concert with Defendant Apotex Corp.,

Apotex Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold throughout the United States and in the State of Florida.

4. On information and belief, Apotex Corp. is a corporation existing under the laws of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, acting in concert with Defendant Apotex Inc., Apotex Corp. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold throughout the United States and in the State of Florida. Upon information and belief, Apotex Corp. is also the United States agent for Apotex Inc. for purposes including, but not limited to, filing regulatory submissions to and corresponding with FDA.

5. Upon information and belief, Apotex Corp. is a wholly owned affiliate of Apotex Inc. Upon information and belief, Apotex Corp. acts at the direction of, under the control of, and for the direct benefit of Apotex Inc. and is controlled and/or dominated by Apotex Inc.

6. Upon information and belief, Apotex Inc. and Apotex Corp. share common officers, including, but not limited to, Dr. Bernard C. Sherman.

NATURE OF THE ACTION

7. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,952,138 ("the '138 Patent") and 6,162,427 ("the '427 Patent").

8. This is among the first actions for patent infringement under 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA").

9. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. The abbreviated pathway (also known as "the (k) pathway") allows a biosimilar applicant (the "subsection (k) applicant") to rely on the prior licensure and approval status of the innovative biological product (called the "reference product") that the biosimilar purports to copy.

10. In addition to creating an abbreviated pathway for approval, the BPCIA created an intricate and carefully orchestrated set of information exchanges to facilitate the resolution of patent disputes before a biosimilar product enters the market. These exchanges are set forth in 42 U.S.C. § 262(*l*)(2)-(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

11. Pursuant to the BPCIA, specifically 42 U.S.C. § 262(k), Apotex submitted abbreviated Biologic License Application no. 761027 (the "Apotex aBLA") seeking authorization from FDA to market a biosimilar version of Amgen's Neupogen® (filgrastim) product ("the Apotex Filgrastim Product").

12. Beginning in March 2015, the parties engaged in the exchange of information and statements as required by the BPCIA. As a result of these exchanges, the parties have agreed to the inclusion of two U.S. patents in this action: the '138 Patent and the '427 Patent ("Patents in Suit").

13. Under 35 U.S.C. § 271(e)(2)(C)(i), it is an act of infringement to submit an application seeking approval of a biological product with respect to patents listed pursuant to 42 U.S.C. § 262(*l*)(3)(A).

14. With respect to the patents that Amgen identified in 42 U.S.C. § 262(*l*)(3)(A), the Patents in Suit, Apotex committed an act of infringement, under 35 U.S.C.

§ 271(e)(2)(C)(i), when it submitted the Apotex aBLA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States the Apotex Filgrastim Product prior to the expiration of each aforementioned patent, or any extensions thereof.

15. Apotex will infringe one or more claims of the Patents in Suit, under 35 U.S.C. § 271(a), (b), (c), or (g), should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of the Apotex Filgrastim Product prior to the expiration of each aforementioned patent, or any extensions thereof.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United states, Title 35 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

Apotex Inc.

19. Upon information and belief, Apotex Inc. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals for sale and use throughout the United States, including in the State of Florida.

20. This Court has personal specific jurisdiction over Apotex Inc. because Apotex Inc. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Amgen. In particular, Apotex Inc. collaborates with Apotex Corp. to develop, manufacture,

seek approval for, and sell the disputed biosimilar product, which will cause tortious injury to Plaintiffs.

21. Moreover, upon information and belief, Apotex Inc., following any FDA approval of the biosimilar product, will sell the Apotex Filgrastim Product that is the subject of the patent infringement claims in this action in Florida and throughout the United States.

22. This Court has personal general jurisdiction over Apotex Inc. by virtue of, *inter alia*, its having conducted business in this District, having availed itself of the rights and benefits of Florida law, and having engaged in substantial and continuing contacts with Florida. Upon information and belief, Apotex Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in Florida and in this District, including with its subsidiary Apotex Corp.

23. Upon information and belief, Apotex Inc. exercises considerable control over Apotex Corp. with respect to biosimilar products, and approves significant decisions of Apotex Corp., including designating Apotex Corp. as the agent for Apotex Inc. in connection with preparing and filing the Apotex aBLA.

24. In addition, Apotex Inc. has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Apotex, Inc. et al v. Mylan Pharmaceuticals, Inc.*, Case No. 12-cv-60704 (S.D. Fla., Apr. 20, 2012). Further, Apotex previously admitted that this Court has personal jurisdiction over both Apotex Corp. and Apotex Inc. *See Alcon v. Apotex Inc. & Apotex Corp.*, C.A. No. 1:06-cv-01642, D.E. 23 at 7 (S.D. Ind. Dec. 13, 2006) ("Plaintiffs could have brought this action in the S.D. Fla. because the S.D. Fla. has personal jurisdiction over both Defendants. Apotex Corp. has a principal place of

business in Weston, Florida, while Apotex Inc. is a Canadian corporation that regularly conducts business in Florida. Thus, venue in the S.D. Fla. would also be proper.").

25. In the alternative, should Apotex Inc. contest jurisdiction in this forum, this Court has personal jurisdiction over Apotex Inc. under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Apotex Inc. "is not subject to jurisdiction in any state's courts of general jurisdiction," and because "exercising jurisdiction is nevertheless consistent with the United States Constitution and laws" given that Apotex Inc. has filed the Apotex aBLA in the United States for a product that it intends to market in the United States.

Apotex Corp.

26. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Corp. has a principal place of business within this judicial district, in Weston, Florida.

27. Upon information and belief, Apotex Corp. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals for use throughout the United States, including in the State of Florida.

28. This Court has personal specific jurisdiction over Apotex Corp. because Apotex Corp. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Amgen. In particular, on information and belief, Apotex Corp. collaborated with Apotex Inc. to develop, manufacture, and seek approval for the Apotex Filgrastim Product, and on information, ApoBiologix®, a division of Apotex Corp., will market the Apotex Filgrastim Product in the United States, which will cause tortious injury to Plaintiffs.

29. This Court has personal general jurisdiction over Apotex Corp. by virtue of, *inter alia*, its having conducted business in this District, having availed itself of the rights and benefits of Florida law, and having engaged in substantial and continuing contacts with Florida. Upon information and belief, Apotex Corp. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in Florida and in this District.

30. In addition, Apotex Inc. has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Apotex, Inc. et al v. Mylan Pharmaceuticals, Inc.*, Case No. 12-cv-60704 (S.D. Fla., Apr. 20, 2012). Further, Apotex previously admitted that this Court has personal jurisdiction over both Apotex Corp. and Apotex Inc. *See Alcon v. Apotex Inc. & Apotex Corp.*, C.A. No. 1:06-cv-01642, D.E. 23 at 7 (S.D. Ind. Dec. 13, 2006) ("Plaintiffs could have brought this action in the S.D. Fla. because the S.D. Fla. has personal jurisdiction over both Defendants. Apotex Corp. has a principal place of business in Weston, Florida, while Apotex Inc. is a Canadian corporation that regularly conducts business in Florida. Thus, venue in the S.D. Fla. would also be proper.").

31. On information and belief, following FDA approval of the Apotex aBLA, Apotex Corp. will sell the Apotex Filgrastim Product that is the subject of the infringement claims in this action in the State of Florida and throughout the United States.

THE PATENTS-IN-SUIT

U.S. PATENT NO. 8,952,138

32. Amgen is the owner of all rights, title, and interest in the '138 Patent.

33. The '138 Patent is titled "Refolding Proteins Using a Chemically Controlled Redox State." The '138 Patent was duly and legally issued on February 10, 2015 by

the United States Patent and Trademark Office ("USPTO"). The inventors of the '138 Patent are Joseph Edward Shultz, Roger Hart, and Ronald Nixon Keener III. A true and correct copy of the '138 Patent is attached to this Complaint as Exhibit A.

34. The '138 Patent covers improved redox chemistry-based methodologies for efficiently refolding cysteine-containing proteins expressed in non-mammalian cells at high protein concentrations.

U.S. PATENT NO. 6,162,427

35. Amgen is the owner of all rights, title, and interest in the '427 Patent.

36. The '427 Patent is titled "Combination of G-CSF with a Chemotherapeutic Agent for Stem Cell Mobilization." The '427 Patent was duly and legally issued on December 19, 2000 by the USPTO. The inventors of the '427 Patent are Matthias Baumann and Peter-Paul Ochlich. A true and correct copy of the '427 Patent is attached to this Complaint as Exhibit B.

37. The '427 Patent is generally directed to an improved method of treating a disease requiring peripheral stem cell transplantation. The method employs a combination of G-CSF and a chemotherapeutic agent to mobilize stem cells more efficiently from the bone marrow to peripheral blood in a patient in need of a peripheral stem cell transplant, where such cells may be collected by leukapheresis. After treatment of the patient with, e.g., myeloablative or myelotoxic therapy, these stem cells are returned to the patient to reconstitute the bone marrow and thereby restore hematopoietic function.

AMGEN'S NEUPOGEN® PRODUCT

38. The active ingredient in Amgen's Neupogen® is filgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF"). Neupogen® is indicated to (1) decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving

myelosuppressive anti-cancer drugs; (2) to reduce the time to neutrophil recovery and duration of fever, following induction or consolidation chemotherapy treatment of adults with Acute Myeloid Leukemia (AML); (3) to reduce the duration of neutropenia and neutropenia-related clinical sequelae in cancer patients undergoing bone marrow transplantation; (4) to mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; (5) to reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, and idiopathic neutropenia; and (6) to increase survival in patients acutely exposed to myelosuppressive doses of radiation. By binding to specific receptors on the surface of certain types of cells, Neupogen® stimulates the production of a type of white blood cell known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. Neupogen ® counteracts neutropenia.

39. The availability of Neupogen® represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by thus facilitating more effective chemotherapy regimes.

THE APOTEX FILGRASTIM PRODUCT

40. On information and belief, Apotex filed the Apotex aBLA under Section 351(k) of the Public Health Service Act to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States, a recombinant filgrastim product, the Apotex Filgrastim Product, that is a biosimilar version of Amgen's Neupogen®.

41. On information and belief, the Apotex aBLA listed Amgen's Neupogen® as a reference product.

42. On information and belief, Apotex has represented to FDA that its Filgrastim Product is biosimilar to Amgen's Neupogen®. As such, the Apotex Filgrastim Product should utilize the same mechanism of action as Neupogen® for the conditions of use prescribed, recommended, or suggested in Neupogen®'s approved label and the route of administration, the dosage form, and the strength of the Apotex Filgrastim Product are the same as those of Amgen's Neupogen®. *See* 42 U.S.C. § 262(k)(2)(A)(i).

INFORMATION EXCHANGE UNDER 42 U.S.C. § 262(*l*)

43. On information and belief, Apotex filed an aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, sell, and import into the United States the Apotex Filgrastim Product, a biosimilar version of Amgen's Neupogen® (filgrastim) product.

44. On information and belief, Apotex's aBLA references and relies on the approval and licensure of Amgen's Neupogen® product in support of Apotex's request for FDA approval.

45. On February 13, 2015, the Apotex aBLA was accepted for review by FDA.

46. Subsequently, Amgen received a copy of the Apotex aBLA under a Confidentiality Agreement that the parties had entered into.

47. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on May 1, 2015, Amgen provided Apotex a list of patents for which it believed a claim of patent infringement could reasonably be asserted against the Apotex Filgrastim Product ("Amgen's (*l*)(3)(A) list"). Amgen's (*l*)(3)(A) list consisted of the Patents in Suit.

48. On June 29, 2015, Apotex provided Amgen with its statements designated as being in accordance with 42 U.S.C. § 262(*l*)(3)(B).

49. On August 28, 2015, Amgen provided Apotex with a detailed statement, pursuant to 42 U.S.C. § 262(*l*)(3)(C).

50. Between August 29, 2015 and September 4, 2015, Amgen and Apotex engaged in good faith negotiations, pursuant to 42 U.S.C. § 262(*l*)(4). On September 4, Amgen and Apotex agreed that the Patents in Suit should be the subject of any patent infringement action brought pursuant to 42 U.S.C. § 262(*l*)(6)(A).

NOTICE OF COMMERCIAL MARKETING UNDER 42 U.S.C. § 262(*l*)(8)

51. On April 17, 2015, Apotex sent Amgen a letter purporting to be Apotex's Notice of Commercial Marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

52. Apotex's purported Notice of Commercial Marketing failed to specify a date on or after which it intends to commence commercial marketing of the Apotex Filgrastim Product.

53. 42 U.S.C. § 262(*l*)(8)(A) states that the "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The Court of Appeals for the Federal Circuit has held that under subsection 262(*l*)(8)(A) "a subsection (k) applicant may only give effective notice of commercial marketing after FDA has licensed its product." *Amgen v. Sandoz*, No. 2015-1499, 2015 WL 4430108, at *9 (Fed. Cir. Jul. 21, 2015).

54. On July 29, 2015, Amgen sent Apotex a letter asking Apotex to confirm that it intended to provide an effective notice of commercial marketing after the Apotex Filgrastim Product is licensed by FDA.

55. On August 24, 2015, Apotex sent Amgen a letter responding that "because Apotex followed the pathway and provided Amgen with its application and manufacturing information, providing a notice of commercial marketing is not mandatory."

56. Upon information and belief, the Apotex Filgrastim Product has not yet been licensed by FDA.

57. Upon information and belief, Apotex intends to market its Filgrastim Product immediately upon receiving FDA licensure.

58. Upon information and belief, Apotex will not provide Amgen with an effective Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8)(A) after it receives FDA licensure and 180 days before it begins to commercially market the Apotex Filgrastim Product.

59. Amgen brings this action to lift the cloud created by the imminent threat of Apotex's refusal to provide a legally effective Notice of Commercial Marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Without declaratory relief, the threat of Apotex's violation of 42 U.S.C. § 262(*l*)(8)(A) poses a substantial risk to Amgen, and impedes Amgen's ability to exercise its rights provided under 42 U.S.C. § 262(*l*) and 35 U.S.C. § 271.

FIRST COUNT
(INFRINGEMENT OF THE '138 PATENT)

60. The allegations of ¶¶ 1-59 are incorporated herein by reference.

61. Upon information and belief, Apotex seeks FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Apotex Filgrastim Product, a biosimilar version of Amgen's Neupogen® (Filgrastim) product.

62. Upon information and belief, Apotex intends to manufacture, use, sell, offer for sale, and/or import the Apotex Filgrastim Product prior to the expiration of the '138 Patent.

63. The submission and filing of Apotex's subsection (k) application for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Filgrastim Product before the expiration of the '138 Patent is an act of infringement of one or more claims of the '138 Patent under 35 U.S.C. § 271(e)(2)(C).

64. Apotex Corp.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex aBLA to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '138 Patent under 35 U.S.C. § 271(e)(2)(C)(i).

65. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Apotex Filgrastim Product will infringe one or more claims of the '138 Patent.

66. Amgen will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '138 Patent. Amgen is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Apotex from any further infringement. Amgen does not have an adequate remedy at law.

67. To the extent Apotex commercializes its product prior to the expiration of the '138 Patent, Amgen will also be entitled to damages under 35 U.S.C. § 284.

SECOND COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '138 PATENT)

68. The allegations of ¶¶ 1-67 are incorporated herein by reference.

69. Upon information and belief, Apotex seeks FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Apotex Filgrastim Product, a biosimilar version of Amgen's Neupogen® (Filgrastim) product.

70. Upon information and belief, Apotex intends to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Apotex Filgrastim Product immediately and imminently upon FDA licensure of the Apotex aBLA.

71. If Apotex manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Apotex Filgrastim Product prior to the expiration of the ’138 Patent, Apotex will infringe one or more claims of the ’138 Patent under 35 U.S.C. § 271 (a) and/or (g).

72. An actual controversy has arisen and now exists between the parties concerning whether the Apotex Filgrastim Product will infringe one or more claims of the ’138 Patent.

73. Amgen is entitled to a declaratory judgment that Apotex will infringe one or more claims of the ’138 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Apotex Filgrastim Product prior to the expiration of the ’138 Patent.

74. Amgen is entitled to injunctive relief preventing Apotex from making, using, offering to sell, or selling within the United States, or importing into the United States, the Apotex Filgrastim Product prior to the expiration of the ’138 Patent. Amgen does not have an adequate remedy at law.

THIRD COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’427 PATENT)

75. The allegations of ¶¶ 1-74 are incorporated herein by reference.

76. Upon information and belief, Apotex seeks FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Apotex Filgrastim Product, a biosimilar version of Amgen’s Neupogen® (Filgrastim) product.

77. Upon information and belief, Apotex intends to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Apotex Filgrastim Product immediately and imminently upon FDA licensure of the Apotex aBLA.

78. As indicated on the product label, Amgen's Neupogen® (Filgrastim) product is approved for six indications including for the mobilization of autologous hematopoietic progenitor cells (including stem cells) into the peripheral blood for collection by leukapheresis.

79. A specific use of filgrastim for the mobilization of autologous hematopoietic stem cells into the peripheral blood for collection by leukapheresis is encompassed by one or more claims of the '427 Patent.

80. On information and belief, Apotex seeks approval for many of the same indications and dosage forms for which Amgen's Neupogen® product is approved.

81. FDA guidance suggests that clinical data supporting one indication may be extrapolated across multiple indications and that "if the proposed product meets the statutory requirements for licensure as a biosimilar product under section 351(k) of the PHS act based on, among other things, data derived from a clinical study sufficient to demonstrate safety, purity, and potency in an appropriate condition of use, the potential exists for the biosimilar product to be licensed for one or more additional conditions of use for which the reference product is licensed."[1]

82. The only currently approved filgrastim biosimilar, Zarxio®, was approved for the same non-orphan-use-designated indications as Amgen's Neupogen®, based on

[1] FDA Guidance for Industry – Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (Apr. 2015) at p. 10, available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm444661.pdf (last visited Sept. 29, 2015).

extrapolation of clinical data across indications and the FDA conclusion that the mechanism of action—filgrastim binding to the G-CSF receptor—was the same for each indication.[2] Additionally, the Zarxio® label contains the same information regarding clinical trials, use, dosage and standard of care as the Neupogen® label. On information and belief, FDA may similarly approve Apotex's biosimilar Filgrastim product for the same indications as Amgen's Neupogen® product, and/or require Apotex's label to contain the same information regarding clinical trials, use, dosage and standard of care as the Neupogen® label.

83. Apotex's marketing of its Filgrastim product with a label that includes the same information regarding clinical trials, dosage and standard of care as the Neupogen® label or that includes an indication for mobilization of autologous hematopoietic progenitor (including stem) cells into the peripheral blood for collection by leukapheresis would induce infringement of one or more claims of the '427 Patent.

84. Apotex has not provided Amgen with a legally enforceable commitment precluding Apotex from marketing its Filgrastim product with a label that includes an indication for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

85. Absent a legally cognizable and enforceable commitment by Apotex preventing Apotex from marketing its Filgrastim product with a label that includes the same information regarding clinical trials, dosage and standard of care as the Neupogen® label or that includes an indication for mobilization of autologous hematopoietic progenitor (including stem)

[2] FDA Briefing Document, Oncologic Drugs Advisory Committee Meeting, BLA 12553, EP2006, a proposed biosimilar to Neupogen (filgrastim) (Jan. 7, 2015) at pp. 19-20, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM428780.pdf (last visited Sept. 29, 2015).

cells into the peripheral blood for collection by leukapheresis or that otherwise evidences inducement, an actual controversy exists between the parties.

86. Amgen is entitled to a declaratory judgment that Apotex's marketing of its Filgrastim product with a label that includes the same information regarding clinical trials, dosage and standard of care as the Neupogen® label or that includes an indication for mobilization of autologous hematopoietic progenitor (including stem) cells into the peripheral blood for collection by leukapheresis or that otherwise evidences inducement would infringe, directly or indirectly, one or more claims of the '427 Patent.

87. In the event that Apotex is licensed to market with a label that includes the same information regarding clinical trials, dosage and standard of care as the Neupogen® label or that includes an indication for mobilization of autologous hematopoietic progenitor (including stem) cells into the peripheral blood for collection by leukapheresis, Amgen will be entitled to injunctive relief preventing Apotex from making, using, offering to sell, or selling within the United States, or importing into the United States, the Apotex Filgrastim Product prior to the expiration of the '427 Patent. Amgen will not have an adequate remedy at law.

FOURTH COUNT
(DECLARATORY JUDGMENT THAT APOTEX'S NOTICE OF COMMERCIAL MARKETING VIOLATES 42 U.S.C. § 262(*l*)(8)(A))

88. The allegations of ¶¶ 1-87 are incorporated herein by reference.

89. To comply with 42 U.S.C. § 262(*l*)(8)(A), Apotex must provide notice to Amgen "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

90. Amgen received a letter from Apotex dated April 17, 2015, in which Apotex purported to provide notice of commercial marketing of the Apotex Filgrastim Product, which has not yet been approved for licensure by FDA. This purported notice is ineffective

because, *inter alia*, a subsection (k) applicant may only give effective notice of commercial marketing after FDA has licensed its product, and the purported notice failed to specify a date on or after which Apotex intends to commence commercial marketing of the Apotex Filgrastim Product.

91. Amgen further received a letter from Apotex, dated August 24, 2015, in which Apotex asserted that "because Apotex followed the pathway and provided Amgen with its application and manufacturing information, providing a notice of commercial marketing is not mandatory."

92. Upon information and belief, Apotex will not provide Amgen with a notice of commercial marketing *after* the Apotex Filgrastim Product has been licensed by FDA.

93. Upon information and belief, Apotex intends to begin commercial marketing of the Apotex Filgrastim Product less than 180 days after the Apotex Filgrastim Product has been licensed by FDA.

94. An actual controversy has arisen and now exists between the parties concerning whether a notice of commercial marketing is mandatory under 42 U.S.C. § 262(*l*)(8)(A), and whether Apotex's refusal to provide an effective notice of commercial marketing is a violation of 42 U.S.C. § 262(*l*)(8)(A).

95. Amgen is entitled to a declaratory judgment that Apotex will be in violation of 42 U.S.C. § 262(*l*)(8)(A) if it fails to provide the required Notice of Commercial Marketing.

96. Amgen is entitled to injunctive relief under 42 U.S.C. § 262(*l*)(8)(A) preventing Apotex from engaging in commercial marketing of the Apotex Filgrastim Product

until a date that is at least 180 days after Apotex provides effective notice to Amgen under 42 U.S.C. § 262(*l*)(8)(A). Amgen does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Amgen respectfully requests that this Court enter judgment in its favor against Apotex and grant the following relief:

A. a judgment that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the ’138 Patent under 35 U.S.C. § 271(e)(2)(C)(i), by submitting to FDA the Apotex aBLA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of the Apotex Filgrastim Product before the expiration of the ’138 Patent;

B. a preliminary and/or permanent injunction that enjoins Apotex, their officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing the ’138 Patent, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacture of which infringes the ’138 Patent;

C. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Apotex aBLA would constitute infringement of one or more claims of the ’138 Patent, or inducement of or contribution to such conduct, by Apotex pursuant to 35 U.S.C. § 271 (a), (b), (c), or (g);

D. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the ’427 Patent if it markets its Filgrastim product with a label that includes an indication for the mobilization of autologous hematopoietic progenitor

(including stem) cells into the peripheral blood for collection by leukapheresis or a label that includes the same information regarding clinical trials, dosage and standard of care as the Neupogen® label, and if Apotex commercially manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Apotex Filgrastim Product before the expiration of the ’427 Patent;

E. a preliminary and/or permanent injunction that enjoins Apotex, their officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing the ’427 Patent, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacture of which infringes the ’427 Patent;

F. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Apotex aBLA would constitute infringement of one or more claims of the ’427 Patent, or inducement of or contribution to such conduct, by Apotex pursuant to 35 U.S.C. § 271 (a), (b), (c), or (g) if Apotex’s Filgrastim product label contains an indication for the mobilization of autologous hematopoietic progenitor (including stem) cells into the peripheral blood for collection by leukapheresis or contains the same information regarding clinical trials, dosage and standard of care as the Neupogen® label;

G. a declaration that the notice of commercial marketing that Apotex provided on April 17, 2015 is ineffective under 42 U.S.C. § 262(*l*)(8)(A);

H. a declaration that Apotex will be in violation of 42 U.S.C. § 262(*l*)(8)(A) by not providing Amgen with an effective notice of commercial marketing after the Apotex

Filgrastim Product is licensed by FDA and at least 180 days before Apotex begins commercial marketing of the Apotex Filgrastim Product;

I. a preliminary and/or permanent injunction that enjoins Apotex, its officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from commencing commercial marketing of the Apotex Filgrastim Product until a date that is at least 180 days after Apotex provides effective notice to Amgen under 42 U.S.C. § 262(*l*)(8)(A);

J. a judgment compelling Apotex to pay to Amgen damages adequate to compensate for Apotex's infringement, in accordance with 35 U.S.C. § 284;

K. a declaration that this is an exceptional case and an award to Amgen of its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

L. such other relief as this Court may deem just and proper.

Dated: October 2, 2015

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