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 its 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 principle 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 5,824,784 ("the '784 Patent").

8. This is one of 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)-(*l*)(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), defendants Apotex submitted Biologic License Application (BLA) no. 761026 (the "Apotex BLA") seeking authorization from FDA to market a biosimilar version of Amgen's Neulasta® (pegfilgrastim) product ("the Apotex Pegfilgrastim Product").

12. Beginning in December 2014, 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 '784 Patent ("Patents in Suit").

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

14. With respect to the patents that Amgen identified in 42 U.S.C. § 262(*l*)(3)(A), including 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 BLA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States the Apotex Pegfilgrastim 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 Pegfilgrastim 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 Pegfilgrastim 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 BLA.

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.I. 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 BLA 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 principle 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 sale and 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 Pegfilgrastim Product, and on information, ApoBiologix®, a division of Apotex Corp., will market the Apotex Pegfilgrastim 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.I. 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 BLA, Apotex Corp. will sell the Apotex Pegfilgrastim 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. 5,824,784

35. Amgen is the owner of all rights, title, and interest in the '784 Patent.

36. The '784 Patent is titled "N-Terminally Chemically Modified Protein Compositions and Methods." The '784 Patent was duly and legally issued on October 20, 1998 by the USPTO. The inventors of the '784 Patent are Olaf B. Kinstler, Nancy E. Gabriel, Christrine E. Farrer, and Randolf B. DePrince. A true and correct copy of the '784 Patent is attached to this Complaint as Exhibit B.

37. The '784 Patent relates, in part, to novel compositions of N-terminally chemically modified G-CSF, and to preparations of the same compositions, *e.g.* a substantially homogenous preparation of N-terminally PEGylated G-CSF, and methods of N-terminally modifying G-CSF and analogs thereof.

AMGEN'S NEULASTA® PRODUCT

38. The active ingredient in Amgen's Neulasta® is pegfilgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF") conjugated to a 20 kD monomethoxypolyethylene glycol (m-PEG) at the N-terminus of the G-CSF.

39. Neulasta® is indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. By binding to specific receptors on the surface of

certain types of cells, Neulasta® stimulates the production of a type of white blood cells 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. Neulasta® counteracts neutropenia.

40. The availability of Neulasta® 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 PEGFILGRASTIM PRODUCT

41. On information and belief, Apotex filed the Apotex BLA 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 pegylated filgrastim product, the Apotex Pegfilgrastim Product, that is a biosimilar version of Amgen's Neulasta®.

42. On information and belief, the Apotex BLA listed Amgen's Neulasta® as a reference product.

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

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

44. On information and belief, Apotex filed a BLA 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, and sell, and import into the United States the Apotex Pegfilgrastim Product, a biosimilar version of Amgen's Neulasta® (pegfilgrastim) product.

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

46. On December 16, 2014, Amgen received a letter from in-house counsel for Apotex Inc., notifying Amgen that the Apotex BLA had been accepted for review by FDA and that Apotex intended to provide Amgen the Apotex BLA pursuant to 42 U.S.C. § 262(*l*)(2).

47. Subsequently, Amgen received a copy of the Apotex BLA under the confidentiality provisions set forth in 42 U.S.C. § 262(*l*)(1).

48. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on February 27, 2015, Amgen provided Apotex a list of patents for which it believed a claim of patent infringement could reasonably be asserted against the Apotex Pegfilgrastim Product ("Amgen's (*l*)(3)(A) list"). Amgen's (*l*)(3)(A) list included the Patents in Suit.

49. On April 17, 2015, Apotex provided Amgen with its statements designated as being in accordance with 42 U.S.C. § 262(*l*)(3)(B).

50. On June 16, 2015, Amgen provided Apotex with a detailed statement, pursuant to 42 U.S.C. § 262(*l*)(3)(C).

51. Between June 22, 2015 and July 7, 2015, Amgen and Apotex engaged in good faith negotiations, pursuant to 42 U.S.C. § 262(*l*)(4). On July 7, 2015, 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)

52. 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).

53. 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 Pegfilgrastim Product.

54. 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).

55. On information and belief, the Apotex Pegfilgrastim Product has not yet been licensed by FDA.

56. On information and belief, Apotex intends to market its Pegfilgrastim Product immediately upon receiving FDA approval.

57. On 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 Pegfilgrastim Product.

58. 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)

59. The allegations of ¶¶ 1-58 are incorporated herein by reference.

60. On information and belief, Apotex seeks FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Apotex Pegfilgrastim Product, a biosimilar version of Amgen's Neulasta® (pegfilgrastim) product.

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

62. 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 Pegfilgrastim 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).

63. Apotex Corp.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex BLA 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).

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

65. 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.

66. 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
(INFRINGEMENT OF THE '784 PATENT)

67. The allegations of ¶¶ 1-66 are incorporated herein by reference.

68. On information and belief, Apotex seeks FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Apotex Pegfilgrastim Product, a biosimilar version of Amgen's Neulasta® (pegfilgrastim) product.

69. 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 Pegfilgrastim Product before the expiration of the '784 Patent is an act of infringement of one or more claims of the '784 Patent under 35 U.S.C. § 271(e)(2)(C).

70. Apotex Corp.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex BLA to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '784 Patent under 35 U.S.C. § 271(e)(2)(C)(i).

71. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Apotex Pegfilgrastim Product will infringe one or more claims of the '784 Patent.

72. 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 '784 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.

73. To the extent Apotex commercializes its product prior to the expiration of the '784 Patent, Amgen will also be entitled to damages under 35 U.S.C. § 284.

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

74. The allegations of ¶¶ 1-73 are incorporated herein by reference.

75. On information and belief, Apotex seeks FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Apotex Pegfilgrastim Product, a biosimilar version of Amgen's Neulasta® (pegfilgrastim) product.

76. 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 Pegfilgrastim Product immediately and imminently upon FDA licensure of the Apotex BLA.

77. If Apotex manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Apotex Pegfilgrastim 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).

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

79. 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 Pegfilgrastim Product prior to the expiration of the '138 Patent.

80. 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 Pegfilgrastim Product prior to the expiration of the '138 Patent. Amgen does 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))

81. The allegations of ¶¶ 1-80 are incorporated herein by reference.

82. 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)."

83. Amgen received a letter from Apotex dated April 17, 2015, in which Apotex purported to provide notice of commercial marketing of the Apotex Pegfilgrastim 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 Pegfilgrastim Product.

84. Upon information and belief, Apotex intends to rely upon its April 17, 2015 notice, and will not provide Amgen with a notice *after* the Apotex Pegfilgrastim Product has been licensed by FDA.

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

86. An actual controversy has arisen and now exists between the parties concerning whether Apotex's purported notice of April 17, 2015 is legally effective.

87. Apotex's purported notice of April 17, 2015 is legally ineffective, and Amgen is entitled to a declaratory judgment that Apotex is in violation of 42 U.S.C. § 262(*l*)(8)(A).

88. 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 Pegfilgrastim 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 BLA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of the Apotex Pegfilgrastim 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 BLA 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 judgment that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the ’784 Patent under 35 U.S.C. § 271(e)(2)(C)(i), by submitting to FDA the Apotex BLA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of the Apotex Pegfilgrastim Product before the expiration of the ’784 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 ’784 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 ’784 Patent;

F. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Apotex BLA would constitute infringement of one or more claims of the ’784 Patent, or inducement of or contribution to such conduct, by Apotex pursuant to 35 U.S.C. § 271 (a), (b), (c), or (g);

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 Pegfilgrastim Product is licensed by FDA and at least 180 days before Apotex begins commercial marketing of the Apotex Pegfilgrastim 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 Pegfilgrastim 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: August 6, 2015

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