UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 15-61631-CIV-COHN (consolidated with 15-62081-CIV-COHN)

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

DEFENDANTS APOTEX INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by their attorneys Cozen O'Connor, for their Answer to the Complaint filed by Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen"), state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

THE PARTIES

1. Upon information and belief, Apotex admits that Plaintiff 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. Apotex denies all remaining allegations of Paragraph 1.

2. Upon information and belief, Apotex admits that Plaintiff Amgen Manufacturing Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of

business in Juncos, Puerto Rico. Apotex denies all remaining allegations of Paragraph 2.

3. Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Apotex admits that Apotex Inc. develops, manufactures, and sells pharmaceuticals, including quality generic medicines. Apotex denies all remaining allegations of Paragraph 3.

4. Apotex admits that Apotex Corp. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex admits that Apotex Corp. markets and sells pharmaceuticals in the United States, including quality generic medicines. Apotex denies all remaining allegations of Paragraph 4.

5. Paragraph 5 contains legal conclusions and allegations to which no answer is required. Apotex denies all remaining allegations of Paragraph 5.

6. Apotex admits that Apotex Inc. and Apotex Corp. share some common officers. Apotex denies all remaining allegations of Paragraph 6.

NATURE OF THE ACTION

7. Apotex admits that Plaintiffs purport to bring this action alleging infringement of United States Patent Nos. 8,952,138 ("the '138 patent") and 6,162,427 ("the '427 patent") pursuant to Title 35 of the United States Code. Apotex denies all remaining allegations of Paragraph 7.

8. Apotex admits that the Complaint purports to bring a civil action for patent infringement under 35 U.S.C. § 271(e)(2)(C). Apotex further admits that 35 U.S.C. § 271(e)(2)(C) was enacted in 2010 as part of the Biologics Price Competition and Innovation

Act ("the BPCIA") and that, to date, less than ten actions for patent infringement under 35 U.S.C. § 271(e)(2)(C) have been filed. Apotex denies all remaining allegations of Paragraph 8.

9. The allegations contained in Paragraph 9 are allegations of law or characterizations of the BPCIA that require no response from Apotex. To the extent an answer is required, Apotex denies all characterizations of the law that are inconsistent with referenced statutes and pertinent case law. Apotex denies all remaining allegations of Paragraph 9.

10. The allegations contained in Paragraph 10 are allegations of law or characterizations of the BPCIA that require no response from Apotex. To the extent an answer is required, Apotex denies all characterizations of the law that are inconsistent with referenced statutes and pertinent case law. Apotex denies all remaining allegations of Paragraph 10.

11. Apotex admits that pursuant to 42 U.S.C. § 262(k), Apotex submitted Biologic License Application (BLA) No. 761027 (the "Apotex aBLA") seeking FDA approval to market a biosimilar version of Amgen's Neupogen® (filgrastim) product ("the Apotex Filgrastim Product"). Apotex denies all remaining allegations of Paragraph 11.

12. Apotex admits that on or about March 4, 2015, Apotex provided Amgen with a copy of the Apotex aBLA pursuant to 42 U.S.C. § 262(*l*)(2), which led Apotex and Amgen to engage in the subsequent exchange of information and statements pursuant to the BPCIA. Apotex further admits that pursuant to the BPCIA, on or about September 4, 2015, Apotex and Amgen agreed that should Amgen sue, the '138 and '427 patents would be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). Apotex denies all remaining allegations of Paragraph 12.

13. Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that 35 U.S.C. § 271(e)(2)(C)(i)

states that it shall be an act of infringement to submit "with respect to a patent that is identified in the list of patents described in 351(l)(3) of the Public Health Act . . . an application seeking approval of a biological product." Apotex denies all remaining allegations of Paragraph 13.

14. Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that Amgen identified patents, including the Patents in Suit, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Apotex denies all remaining allegations of Paragraph 14.

15. Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies all allegations of Paragraph 15.

JURISDICTION AND VENUE

16. Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Apotex admits that Plaintiffs purport to bring this action pursuant to Titles 28 and 35 of the United States Code.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Apotex admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 17.

18. Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that venue is proper in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 18.

Apotex Inc.

19. Apotex admits that Apotex Inc. is in the business of developing, manufacturing,

and seeking regulatory approval to distribute and sell quality generic medicines throughout the United States, including in the State of Florida. Apotex Inc. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 19.

20. Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Inc. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies the remaining allegations of Paragraph 20.

21. Apotex admits that it is seeking approval from the FDA to market its Filgrastim Product after FDA-approval of Apotex's aBLA. Further, Apotex Inc. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 21.

22. Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Inc. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 22.

23. Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Inc. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 23.

24. Apotex admits that Apotex Inc. has previously not contested to the jurisdiction of this Court. Apotex Inc. and Apotex Corp. do not contest personal jurisdiction or venue in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of

Paragraph 24.

25. Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Inc. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 25.

Apotex Corp.

26. Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Corp. admits that it is a corporation organized and existing under the laws of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 26.

27. Apotex admits that Apotex Corp. seeks regulatory approval for, markets, distributes, and sells quality generic medicines throughout the United States, including in the State of Florida. Apotex Corp. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 27.

28. Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Corp. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 28.

29. Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex Corp. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all

remaining allegations of Paragraph 29.

30. Apotex admits that Apotex Inc. has previously submitted to the jurisdiction of this Court in a case that is not factually related in any respect to the present action. Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 30.

31. Apotex admits that it is seeking approval from the FDA to market its Filgrastim Product after FDA-approval of Apotex's aBLA. Apotex Corp. does not contest personal jurisdiction in this Court for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 31.

THE PATENTS-IN-SUIT

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

32. Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that according to the electronic records of the United States Patent and Trademark Office ("PTO"), Amgen Inc. is the assignee of the '138 patent. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations of Paragraph 32 and, therefore Apotex denies these allegations.

33. Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the '138 patent is titled "Refolding Proteins Using a Chemically Controlled Redox State," that the '138 patent issued on or about February 10, 2015, that the '138 patent lists Joseph Edward Shultz, Roger Hart, and Ronald Nixon Keener, III as inventors, and that what appears to be a true and correct copy of the '138 patent is attached to Plaintiffs' Complaint as Exhibit A. Apotex denies all remaining

allegations of Paragraph 33.

34. The content of the '138 patent speaks for itself. Apotex denies all remaining allegations of Paragraph 34.

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

35. Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that according to the electronic records of the PTO, Amgen Inc. is the assignee of the '427 patent. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations of Paragraph 35 and, therefore Apotex denies these allegations.

36. Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the '427 patent is titled "Combination of G-CSF with a Chemotherapeutic Agent for Stem Cell Mobilization," that the '427 patent issued on or about December 19, 2000, that the '427 patent lists Matthias Baumann and Peter-Paul Ochlich as inventors, and that what appears to be a true and correct copy of the '427 patent is attached to Plaintiffs' Complaint as Exhibit B. Apotex denies the remaining allegations of Paragraph 36.

37. The content of the '427 patent speaks for itself. Apotex denies all remaining allegations of Paragraph 37.

AMGEN'S NEUPOGEN® PRODUCT

38. Apotex admits that the active ingredient in Amgen's Neupogen® is filgrastim. To the extent Paragraph 38 refers to the indications for Neupogen® listed in the FDA-approved package insert, this document speaks for itself. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations of Paragraph 38

and, therefore Apotex denies these allegations.

39. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the allegations of Paragraph 39 and, therefore Apotex denies these allegations.

THE APOTEX FILGRASTIM PRODUCT

40. Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that pursuant to Section 351(k) of the Public Health Service Act, Apotex submitted the Apotex aBLA seeking FDA approval to market Apotex's Filgrastim Product, a biosimilar version of Amgen's Neupogen®. Apotex denies all remaining allegations of Paragraph 40.

41. Apotex admits that the Apotex aBLA lists Amgen's Neupogen® as the reference product. Apotex denies all remaining allegations of Paragraph 41.

42. Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that their Filgrastim Product is biosimilar to Amgen's Neupogen®. Apotex denies all remaining allegations of Paragraph 42.

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

43. Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that pursuant to Section 351(k) of the Public Health Service Act, Apotex submitted the Apotex aBLA seeking FDA approval to market Apotex's Filgrastim Product, a biosimilar version of Amgen's Neupogen®. Apotex denies all remaining allegations of Paragraph 43.

44. Apotex admits that it is seeking FDA approval to market Apotex's Filgrastim Product, which is a biosimilar version of Amgen's Neupogen®. Apotex further admits that Neupogen® is listed as the reference product in the Apotex aBLA. Apotex denies all remaining

allegations of Paragraph 44.

45. Apotex admits that on or about February 13, 2015, the Apotex aBLA was accepted for review by the FDA. Apotex denies all remaining allegations of Paragraph 45.

46. Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that on or about March 4, 2015, Apotex provided Amgen with a copy of the Apotex aBLA pursuant to a Confidentiality Agreement that the parties had entered into. Apotex denies all remaining allegations of Paragraph 46.

47. Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that pursuant to 42 U.S.C. § 262(*l*)(3)(A), in a letter dated May 1, 2015, Amgen provided Apotex a list of patents for which Amgen purports a claim of patent infringement could reasonably be asserted against the Apotex Filgrastim Product ("Amgen's (*l*)(3)(A) list"). Apotex denies all remaining allegations of Paragraph 47.

48. Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that pursuant to 42 U.S.C. § 262(*l*)(3)(B), on or about June 29, 2015, Apotex provided Amgen with a statement regarding each patent listed by Amgen under 42 U.S.C. § 262(*l*)(3)(A) in Amgen's letter dated May 1, 2015 ("Apotex's Detailed Statement"). Apotex denies all remaining allegations of Paragraph 48.

49. Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that on or about August 28, 2015, Amgen provided Apotex with a statement designated as being in accordance with 42 U.S.C. §262(*l*)(3)(C). Apotex denies all remaining allegations of Paragraph 49.

50. Apotex admits that between about August 29, 2015 and about September 4, 2015, Amgen and Apotex engaged in negotiations, pursuant to 42 U.S.C. § 262(*l*)(4). Apotex further admits that on or about September 4, 2015, Amgen and Apotex reached agreement that should Amgen sue, the '138 patent and the '427 patent would be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6)(A). Apotex denies all remaining allegations of Paragraph 50.

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

51. Apotex admits that in a letter dated April 17, 2015, Apotex provided a Notice of Commercial Marketing to reference product sponsor, Amgen Inc., for Apotex's Filgrastim Product described in its sections 351(k) application, BLA No. 761027, pursuant to 42 U.S.C. § 262(*l*)(8)(A). Apotex denies all remaining allegations of Paragraph 51.

52. The content of Apotex's Notice of Commercial Marketing speaks for itself. Apotex denies all remaining allegations of Paragraph 52.

53. The allegations contained in Paragraph 53 are allegations of law or characterizations of the BPCIA that require no response from Apotex. To the extent an answer is required, Apotex denies all characterizations of the law that are inconsistent with referenced statutes and pertinent case law. Apotex admits that Plaintiffs have accurately quoted a portion of 42 U.S.C. § 262(*l*)(8)(A). Apotex further admits that Plaintiffs have accurately quoted a portion of *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499, 2015 WL 4430108, at *9 (Fed. Cir. Jul. 21, 2015). Apotex denies all remaining allegations of Paragraph 53.

54. The content of Amgen's letter dated July 29, 2015 speaks for itself. Apotex denies all remaining allegations of Paragraph 54.

55. The content of Apotex's letter dated August 24, 2015 speaks for itself. Apotex

denies all remaining allegations of Paragraph 55.

56. Apotex admits that, to date, the Apotex Filgrastim Product has not been licensed by the FDA. Apotex denies all remaining allegations of Paragraph 56.

57. Apotex admits that it intends to market its Filgrastim Product after FDA-approval of Apotex's aBLA. Apotex denies all remaining allegations of Paragraph 57.

58. Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, where a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262 (*l*)(2)(A), the BPCIA gives such biosimilar applicant the option to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8)(A) or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation of the BPCIA would render superfluous subsection (*l*)(9)(B), which states:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(Emphasis added). Thus, the BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (*l*)(9)(B). Apotex denies all remaining allegations of Paragraph 58.

59. Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies all allegations of Paragraph 59.

FIRST COUNT
(INFRINGEMENT OF THE '138 PATENT)

60. Apotex incorporates by reference its answers to the allegations of ¶¶ 1-59 as if fully set forth herein.

61. Apotex admits that pursuant to Section 351(k) of the Public Health Service Act, Apotex is seeking FDA approval to market Apotex's Filgrastim Product, a biosimilar version of Amgen's Neupogen®. Apotex denies all remaining allegations of Paragraph 61.

62. Admitted.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

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

68. Apotex incorporates by reference its answers to the allegations of ¶¶ 1-67 as if fully set forth herein.

69. Apotex admits that pursuant to Section 351(k) of the Public Health Service Act, Apotex is seeking FDA approval to market Apotex's Filgrastim Product, a biosimilar version of Amgen's Neupogen®. Apotex denies all remaining allegations of Paragraph 69.

70. Apotex admits that it is seeking approval from the FDA to market its Filgrastim Product after FDA-approval of Apotex's aBLA. Apotex denies all remaining allegations of Paragraph 70.

71. Denied.

72. Admitted.

73. Denied.

74. Denied

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

75. Apotex incorporates by reference its answers to the allegations of ¶¶ 1-74 as if fully set forth herein.

76. Apotex admits that pursuant to Section 351(k) of the Public Health Service Act, Apotex is seeking FDA approval to market Apotex's Filgrastim Product, a biosimilar version of Amgen's Neupogen®. Apotex denies all remaining allegations of Paragraph 76.

77. Apotex admits that it is seeking approval from the FDA to market its Filgrastim Product after FDA-approval of Apotex's aBLA. Apotex denies all remaining allegations of Paragraph 77.

78. The content of Neupogen®'s label speaks for itself. Apotex denies all remaining allegations of Paragraph 78.

79. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations of Paragraph 79 and, therefore Apotex denies these allegations.

80. The content of Apotex's aBLA speaks for itself. Apotex denies all remaining allegations of Paragraph 80.

81. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations of Paragraph 81 and, therefore Apotex denies these allegations.

82. Apotex lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations of Paragraph 82 and, therefore Apotex denies these

allegations.

83. Denied.

84. Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, and based on the foregoing, Apotex denies these allegations.

85. Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, and based on the foregoing, Apotex denies these allegations.

86. Denied.

87. Denied.

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

88. Apotex incorporates by reference its answers to the allegations of ¶¶ 1-87 as if fully set forth herein.

89. Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that Plaintiffs have accurately quoted a portion of 42 U.S.C. § 262(*l*)(8)(A). Apotex denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Where a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262(*l*)(2)(A), the BPCIA gives such biosimilar applicant the *option* to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8)(A) or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation of the BPCIA would render superfluous subsection (*l*)(9)(B), which states:

> If a subsection (k) applicant fails to complete an action required of

> the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(Emphasis added). Thus, the BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (*l*)(9)(B). Apotex denies all remaining allegations of Paragraph 89.

90. Paragraph 90 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Apotex admits that in a letter dated April 17, 2015, Apotex provided Notice of Commercial Marketing to reference product sponsor, Amgen Inc., for Apotex's Filgrastim Product, described in the Apotex aBLA, pursuant to 42 U.S.C. § 262(*l*)(8)(A). Apotex further admits that its Filgrastim Product has not yet been approved for licensure by the FDA. Apotex denies all remaining allegations of Paragraph 90.

91. The content of Apotex's letter dated August 24, 2015 speaks for itself. Apotex denies all remaining allegations of Paragraph 91.

92. Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, where a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262(*l*)(2)(A), the BPCIA gives such biosimilar applicant the *option* to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8)(A) or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation of the BPCIA

would render superfluous subsection (*l*)(9)(B), which states:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(Emphasis added). Thus, the BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (*l*)(9)(B). Apotex denies all remaining allegations of Paragraph 92.

93. Apotex admits that it is seeking approval from the FDA to market its Filgrastim Product after FDA-approval of Apotex's aBLA. Apotex denies all remaining allegations of Paragraph 93.

94. Paragraph 94 contains legal conclusions and allegations to which no answer is required. Apotex denies all remaining allegations of Paragraph 94.

95. Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, where a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262(*l*)(2)(A), the BPCIA gives such biosimilar applicant the *option* to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8)(A) or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation of the BPCIA would render superfluous subsection (*l*)(9)(B), which states:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may

> bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(Emphasis added). Thus, the BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (*l*)(9)(B). Apotex denies all remaining allegations of Paragraph 95.

96. Paragraph 96 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, where a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262(*l*)(2)(A), the BPCIA gives such biosimilar applicant the *option* to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8)(A) or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation of the BPCIA would render superfluous subsection (*l*)(9)(B), which states:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(Emphasis added). Thus, the BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right, under BPCIA subsection (*l*)(9)(B), to bring an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Contrary to Plaintiffs' interpretation, the BPCIA does not allow the reference product sponsor to obtain an injunction if the biosimilar applicant elects not to provide a notice of commercial marketing. Apotex denies

all remaining allegations of Paragraph 96.

PRAYER FOR RELIEF

Apotex denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

APOTEX'S AFFIRMATIVE DEFENSES

Apotex asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
(No Infringement Under 35 U.S.C. § 271(e)(2)(C)(i))

The submission of Apotex's aBLA seeking approval to market Apotex's Filgrastim Product does not infringe, directly or indirectly, any valid and/or enforceable claim of the '138 patent or the '427 patent, either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE
(No Direct Infringement)

Apotex has not, does not, and will not infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '138 or '427 patents.

FOURTH AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Apotex has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '138 or '427 patents.

FIFTH AFFIRMATIVE DEFENSE
(Invalidity)

The '138 and '427 patents and each of the claims thereof are invalid for failure to comply

with one or more conditions for patentability set forth in one or more provision of 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to preliminary and/or permanent equitable relief, including but not limited to 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 any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any product that purportedly infringes, or the use or manufacture of which purportedly infringes the '138 patent or the '427 patent.

SEVENTH AFFIRMATIVE DEFENSE

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

RESERVATION OF DEFENSES

Apotex hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

APOTEX INC.'S AND APOTEX CORP.'S COUNTERCLAIMS

Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by way of their attorneys Cozen O'Connor, hereby state for their Counterclaims against Amgen Inc. and Amgen Manufacturing Limited (collectively, "Counterclaim Defendants" or "Amgen") the following:

THE PARTIES

1. Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

2. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principle place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Counterclaim Defendant Amgen Inc. purports to be 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.

4. Counterclaim Defendant Amgen Manufacturing Limited ("AML") purports to be a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Biologics Price Competition and Innovation Act ("BPCIA") 42 U.S.C. § 262; Section 2 of the Sherman Act, 15 U.S.C. § 2; and under the Clayton Act, 15 U.S.C. §§ 15 and 26.

6. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1131, 1338(a)-(b); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, and 2202;

under Section 4 of the Sherman Act, 15 U.S.C. § 4; under the Clayton Act, 15 U.S.C. §§ 15(a) and 26; and under the BPCIA, 42 U.S.C. § 262.

7. This Court has personal jurisdiction over each of Counterclaim Defendants, Amgen Inc. and Amgen Manufacturing Limited, at least because they have availed themselves of the rights and privileges of this forum by filing the Complaint in this judicial district.

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

BACKGROUND

Counterclaim Defendants and Biologics

9. Counterclaim Defendants are engaged in the development, commercialization, and marketing of pharmaceutical products, including biological products, for the treatment of various disorders.

10. Before marketing a biological product in the United States, a manufacturer must submit a Biologic License Application ("BLA") and the U.S. Food and Drug Administration ("FDA") must approve it.

11. Among other things, the BLA must contain a full description of manufacturing methods and nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets required safety, purity, and potency standards.

12. The FDA only approves a biologic if it determines that the product meets applicable requirements to ensure safety, purity, and potency of such products.

13. On or about February 20, 1991, the FDA approved Amgen's BLA No. 103353 for filgrastim, marketed under the trade name Neupogen®.

14. Amgen's 12 year market exclusivity for Neupogen® has expired. See 42 USC

§ 262(k)(7)(a).

15. According to the FDA-approved label for Neupogen®, it is indicated to (1) decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; (2) reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML); (3) reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT); (4) mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; (5) reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia; and (6) increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).

16. According to the FDA-approved label for Neupogen®, in patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML, Neupogen® is administered at least 24 hours after cytotoxic chemotherapy.

17. According to the FDA-approved label for Neupogen®, in patients with cancer undergoing bone marrow transplantation, Neupogen® is administered at least 24 hours after cytotoxic chemotherapy.

18. The FDA-approved label for Neupogen® states "do not use NEUPOGEN in the period 24 hours before through 24 hours after the administration of cytotoxic chemotherapy."

See Neupogen Label.

19. For the fiscal year ending December 31, 2014, Amgen's net revenues were $839 million for Neupogen® in the U.S. alone. *See* Amgen's 10-K at pp. 45 and F-49.

Apotex and Biosimilars

20. Apotex is engaged in the development, commercialization, and marketing of generic pharmaceutical products, including biosimilars, for the treatment of various disorders.

21. Biosimilars are biological products intended to be clinically similar to a previously FDA-approved biological reference product ("reference product"). In this sense, biosimilars are like "generics" for small molecule drugs.

22. Biosimilars are licensed by the FDA under the provisions of the BPCIA.

23. Enacted in 2010 as part of the Patient Protection and Affordable Care Act, the BPCIA creates an abbreviated licensure pathway for biological products shown to be biosimilar to the reference product. *See* BPCIA §§ 7001-7003, Pub. L. No. 111-148, 124 Stat 119, 804-21 (2010).

24. The licensure pathway is considered "abbreviated" because the biosimilar applicant (also known as a "subsection (k) applicant") is not required to provide the full scale of preclinical and clinical test data required for approval of the reference product. Rather, the biosimilar applicant must demonstrate that the biosimilar is "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *See* 42 U.S.C. § 262 (i)(2).

25. Congress enacted the BPCIA with the intent to provide a "biosimilars pathway balancing innovation and consumer interests." *See* BPCIA, § 7001(b), Pub. L. No. 111-148, 124

Stat at 804.

26. Biosimilars, like generic drugs, are expected to provide a price advantage over the reference product. Consequently, biosimilars are also expected to be utilized in an effort to control health-care costs.

27. Similarly, the introduction of biosimilars as alternatives to reference products, like the introduction of generic drugs as alternatives to brand-name drugs, is expected to reduce the market share of reference products.

28. On or about December 12, 2014, Apotex submitted BLA No. 761027 ("Apotex's aBLA"), seeking FDA approval to market a biosimilar filgrastim product, for which Neupogen® is the reference product ("Apotex's Filgrastim Product").

The Patents-In-Suit

U.S. Patent No. 8,952,138

29. On information and belief, Amgen is the owner of U.S. Patent No. 8,952,138 ("the '138 patent").

30. The '138 patent is entitled "Refolding Proteins Using a Chemically Controlled Redox State" and issued on February 10, 2015.

31. The sole independent claim of the '138 patent purports to claim, *inter alia*, "A method of refolding a protein expressed in a non-mammalian expression system and present in a volume at a concentration of 2.0 g/L or greater comprising: (a) contacting the protein with a refold buffer comprising a redox component comprising a final thiol-pair ratio having a range of 0.001 to 100 and a redox buffer strength of 2 mM or greater . . ." *See* '138 patent, claim 1.

32. The '138 patent does not disclose a method of refolding any specific protein, much less the protein found in Apotex's Filgrastim Product.

U.S. Patent No. 6,162,427

33. On information and belief, Amgen is the owner of U.S. Patent No. 6,162,427 ("the '427 patent").

34. The '427 patent is entitled: "N-Terminally Chemically Modified Protein Compositions and Methods" and issued on December 19, 2000.

35. The '427 patent issued with 7 claims, of which claims 1 and 7 are the sole independent claims.

36. Independent claim 1 purports to claim, *inter alia*, a method of treating a disease requiring a peripheral stem cell transplantation wherein a hematopoietic stem cell mobilizing-amount of G-CSF (i.e. filgrastim) is administered *followed* by a disease treating-effective amount of at least one chemotherapeutic agent.

COUNT I
(Declaratory Judgment of Noninfringement of the '138 patent)

37. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses and ¶¶ 1-36 of these Counterclaims.

38. In their Complaint, Counterclaim Defendants assert that Apotex committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C) by submitting Apotex's aBLA to the FDA.

39. Apotex asserts that the manufacture, use, offer for sale, sale, or importation of Apotex's Filgrastim Product does not and will not infringe any valid claim of the '138 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g), or (e)(2)(C)(i).

40. The '138 patent includes claims that purport to cover methods of refolding proteins expressed in non-mammalian expression systems and present at a concentration of 2.0 g/L or greater comprising, *inter alia*, contacting the protein with a refold buffer comprising a

redox component with a final thiol-pair ratio of 0.001 to 100 and a redox buffer strength of 2 mM or greater.

41. The ’138 patent does not claim the method of manufacturing Apotex’s Filgrastim Product.

42. The method of manufacturing Apotex’s Filgrastim Product requires a protein concentration that does not fall within the “2.0 g/L or greater” concentration claimed in the ’138 patent. Instead, Apotex’s aBLA requires, through specification and quality control measures, that the protein concentration in the refold buffer fall well outside the concentration claimed in the ’138 patent.

43. The method of manufacturing Apotex’s Filgrastim Product also includes a redox buffer strength that does not fall within the “2 mM or greater” concentration claimed in the ’138 patent. Instead, Apotex’s aBLA requires, through specification and quality control measures, that the redox buffer strength fall well outside the range claimed in the ’138 patent.

44. An actual, substantial, and continuing justiciable case or controversy exists between Counterclaim Defendants and Apotex regarding infringement of the ’138 patent.

45. Apotex is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Apotex’s Filgrastim Product that is the subject of Apotex’s aBLA has not, does not, and will not infringe any valid and/or enforceable claim of the ’138 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g), or (e)(2)(C).

46. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

47. This is an exceptional case, and Apotex is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT II
(Declaratory Judgment of Invalidity of the '138 patent)

48. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and ¶¶ 1-47 of these Counterclaims.

49. In their Complaint, Counterclaim Defendants assert that Apotex committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(i) by submitting Apotex's aBLA to the FDA.

50. Apotex asserts that the claims of the '138 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

51. An actual, substantial, and continuing justiciable case or controversy between Counterclaim Defendants and Apotex regarding the validity of the '138 patent.

52. Apotex is entitled to a declaration that the claims of the '138 patent are invalid.

53. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT III
(Declaratory Judgment of Noninfringement of the '427 patent)

54. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses and ¶¶ 1-53 of these Counterclaims.

55. Apotex asserts that the manufacture, use, offer for sale, sale, or importation of Apotex's Filgrastim Product does not and will not infringe any valid claim of the '427 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g), or (e)(2)(C)(i).

56. The '427 patent includes method claims that purport to cover administration of G-CSF (i.e. filgrastim) prior to administration of a chemotherapeutic agent for the treatment of a disease requiring stem cells transplantation.

57. The ’427 patent does not claim the method of administering Apotex’s Filgrastim Product.

58. Apotex’s Filgrastim Product is not indicated for use in patients requiring a peripheral stem cell transplantation as claimed in the ’427 patent. Instead, Apotex’s Filgrastim Product is indicated for use in: (i) cancer patients receiving myelosuppressive chemotherapy; (ii) patients with acute myeloid leukemia receiving induction or consolidation chemotherapy; (iii) cancer patients receiving a bone marrow transplant; and (iv) patients with severe chronic neutropenia.

59. Further, Apotex’s Filgrastim Product is not indicated for use *prior* to administrating a chemotherapeutic agent as claimed in the ’427 patent. Instead, the proposed label for Apotex’s Filgrastim Product will instruct health care workers to administer the Filgrastim Product at least 24 hours *after* administering cytotoxic chemotherapy in patients receiving myelosuppressive chemotherapy or a bone marrow transplant.

60. An actual, substantial, and continuing justiciable case or controversy exists between Counterclaim Defendants and Apotex regarding infringement of the ’427 patent.

61. Apotex is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Apotex’s Filgrastim Product that is the subject of Apotex’s aBLA has not, does not, and will not infringe any valid and/or enforceable claim of the ’427 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g), or (e)(2)(C).

62. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

63. This is an exceptional case, and Apotex is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT IV
(Declaratory Judgment of Invalidity of the '427 patent)

64. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and ¶¶ 1-63 of these Counterclaims.

65. Apotex asserts that the claims of the '427 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

66. An actual, substantial, and continuing justiciable case or controversy between Counterclaim Defendants and Apotex regarding the validity of the '427 patent.

67. Apotex is entitled to a declaration that the claims of the '427 patent are invalid.

68. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT V
(Unlawful Monopolization in Violation of the Sherman Act: Sham Litigation)

69. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and ¶¶ 1-68 of these Counterclaims.

70. This claim arises under Section 2 of the Sherman Act, 15 U.S.C. § 2, and under Clayton Act, 15 U.S.C. §§ 15 and 26.

The Relevant Market and Counterclaim Defendants' Monopoly Power

71. Counterclaim Defendants are engaged in the development, commercialization, and marketing of pharmaceutical products, including biological products, for the treatment of various disorders.

72. Apotex is engaged in the development, commercialization, and marketing of generic pharmaceutical products, including biosimilars, for the treatment of various disorders.

73. The relevant geographic market is the United States.

74. The relevant product market is the market for filgrastim.

75. On information and belief, Counterclaim Defendants are one of only three entities in the United States marketing a filgrastim biological product.

76. On information and belief, Counterclaim Defendants have a majority share of the relevant market.

77. On information and belief, Counterclaim Defendants net revenues for the fiscal year ending December 31, 2014 from the sale of Neupogen® in the U.S. were $839 million. *See* Amgen's 10-K at pp. 45 and F-49.

78. Counterclaim Defendants have, and have exercised, monopoly power in the relevant market.

79. Counterclaim Defendants have the power to control prices and/or exclude competition in, or prevent entry into, the relevant market.

80. There are substantial barriers to entry into the relevant market, including, but not limited to, regulatory requirements and Counterclaim Defendants' actions to preclude Apotex's entry, including, but not limited to, Counterclaim Defendants' present action for infringement of the '138 and '427 patents.

Apotex's Efforts to Compete with Counterclaim Defendants

81. On or about December 12, 2014, Apotex submitted BLA No. 761027 seeking FDA approval to market a biosimilar filgrastim product, for which Neupogen® is the reference product.

82. By filing its aBLA, Apotex is, or will become, a direct competitor with Counterclaim Defendants in the relevant market.

83. On February 13, 2015, Apotex received notification from the FDA that their

aBLA had been accepted for review.

84. On March 4, 2015, in accordance with 42 U.S.C. § 262(*l*)(2)(A), Apotex provided Counterclaim Defendants with the Apotex aBLA, which contains detailed information about Apotex's Filgrastim Product, including specifications pertaining to the refolding conditions used to manufacture Apotex's Filgrastim Product, which indicates that the protein concentration and refold buffer strength do not fall within the ranges claimed in Amgen's '138 patent.

85. In a letter dated May 1, 2015, Counterclaim Defendants provided Apotex a list of patents for which Counterclaim Defendants purported a claim of patent infringement could reasonably be asserted against the Apotex Filgrastim Product ("Amgen's (*l*)(3)(A) list"). This list included the Patents-in-Suit, *i.e.*, the'138 and '427 patents.

86. On June 29, 2015, pursuant to 42 U.S.C. § 262(*l*)(3)(B), Apotex provided Counterclaim Defendants with a detailed statement regarding each patent included in Amgen's (*l*)(3)(A) list ("Apotex's Detailed Statement").

87. Apotex's Detailed Statement contained the legal and factual bases for Apotex's contention that the claims of the '138 and '427 patent are invalid, unenforceable, and/or will not be infringed by the commercial marketing of Apotex's Filgrastim Product.

88. As set forth in Apotex's Detailed Statement, the manufacture of Apotex's Filgrastim Product will not infringe the '138 patent at least because (1) the concentration of filgrastim in the refold buffer does not fall within the protein concentration range (i.e. 2.0 g/L or greater) that is required by all of the claims of the '138 patent and (2) the refold buffer strength does not fall within concentration range (i.e. 2 mM or greater) that is required by all of the claims of the '138 patent.

89. Further, as set forth in Apotex's Detailed Statement, Apotex Filgrastim Product

will not infringe the '427 patent at least because (1) Apotex's Filgrastim Product is not indicated for use in patients requiring a peripheral stem cell transplantation as required by the claims of the '427 patent and (2) Apotex's Filgrastim Product is not administered *prior* to chemotherapy as required by the claims of the '427 patent.

90. Despite the conclusive and irrefutable proof provided to Counterclaim Defendants that the method of producing Apotex's Filgrastim Product covered by Apotex's aBLA does not and cannot infringe the '138 patent, and that Apotex's Filgrastim Product does not and will not infringe the '427 patent, Counterclaim Defendants nonetheless filed this lawsuit which included objectively baseless claims alleging infringement of the '138 and '427 patents. Plaintiffs filed this objectively baseless claim for the purpose of significantly delaying Apotex's entry into relevant markets.

Nature of Counterclaim Defendants Anticompetitive Activity

91. Apotex suffered anticompetitive injury by Counterclaim Defendants' actions, including, but not limited to, the filing and continuing prosecution of this action.

92. Counterclaim Defendants' actions, as described herein, evidence their specific intent to restrain competition, attempt to monopolize, and to monopolize the relevant market.

93. Counterclaim Defendants have engaged in an overall predatory scheme to monopolize the relevant market through actions including, but not limited to, initiating objectively baseless and sham judicial proceedings designed to effectuate their monopoly of filgrastim.

94. These judicial proceedings are not a genuine effort to obtain an adjudication of a valid patent claim that is infringed; rather, they were instituted to achieve an unlawful objective to the detriment of competition in the relevant market. The purpose of such action is to directly

interfere with and to harm the business of competitors in the relevant market, including Apotex, and to forestall, frustrate and prevent competition by such competitors.

95. Counterclaim Defendants' anticompetitive and monopolistic actions evince their overall predatory scheme to injure or destroy competition in the relevant market. Counterclaim Defendants have baselessly and improperly wielded the '138 and '427 patents, including a claim under 35 U.S.C. § 285, as anticompetitive weapons in order to consolidate, entrench, and enhance their monopolistic position in the relevant market and to stifle and eliminate competition and competitors with no economic, market, or competitive benefit.

96. Counterclaim Defendants' exclusionary, anticompetitive, and unlawful action will severely discourage Apotex from marketing its filgrastim biosimilar product upon FDA approval because of the threat of substantial damages by Amgen, which made $839 million in net revenues from the sale of Neupogen® in 2014 in the U.S. alone.

97. Counterclaim Defendants' exclusionary, anticompetitive, and unlawful action will burden Apotex with substantial litigation costs to defend itself against objectively baseless infringement claims on the '138 and '427 patents.

98. By pursuing these objectively baseless infringement claims on the '138 and '427 patents, Counterclaim Defendants also seek to deter downstream customers from buying filgrastim biosimilar products.

99. Instead of allowing Apotex to enter the market for filgrastim biosimilar products, Counterclaim Defendants, with specific intent to maintain monopoly power over the relevant market, instituted this suit against Apotex on October 5, 2015, alleging, *inter alia*, infringement of the '138 and '427 patents. On information and belief, Counterclaim Defendants filed this lawsuit with an intent to delay, hamper, hinder and impede Apotex from entering the

market with its proposed filgrastim product.

100. Counterclaim Defendants initiated litigation after Apotex provided their aBLA which clearly indicates that the manufacture of Apotex's Filgrastim Product is not covered by the '138 patent claims and that Apotex's Filgrastim Product does not and will not infringe the '427 patent.

101. Counterclaim Defendants initiated litigation after Apotex provided its Detailed Statement which provides the detailed factual and legal bases for Apotex's position on the non-infringement of Apotex's Filgrastim Product and the invalidity of the '138 and '427 patents.

102. On information and belief, the patent infringement claims that Counterclaim Defendants asserted in this lawsuit against Apotex are objectively baseless. No reasonable litigant could expect to secure favorable relief against Apotex upon the merits under the '138 and '427 patents.

103. Counterclaim Defendants brought their patent infringement claims in bad faith, for an improper purpose, and as a means of directly interfering with and harming Apotex's business and in order to forestall, frustrate and prevent competition by Apotex. Counterclaim Defendants' ulterior motive is, and has been, to limit competition in the relevant market and to maintain a monopoly in the relevant market.

104. Counterclaim Defendants' motives are evidenced in Amgen's 10-K Annual Report dated February 19, 2015, which states: "we expect to face greater competition in the United States as a result of biosimilars and downward pressure on our product prices and sales, *subject to our ability to enforce our patents*. This additional competition could have a material adverse effect on our business and results of operations." *See* Amgen's 10-K Annual Report dated February 19, 2015 at p.27 (emphasis added).

105. Upon information and belief, Counterclaim Defendants intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the market of filgrastim.

106. Counterclaim Defendants' litigation filed against Apotex alleging infringement of the '138 and '427 patents is both objectively and subjectively baseless. Counterclaim Defendants' litigation filed against Apotex alleging infringement of the '138 and '427 patents constitutes sham litigation and bad faith enforcement of Amgen's patents.

107. Counterclaim Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Apotex's foreclosure from the relevant market.

108. Counterclaim Defendants have created a dangerous probability that they will achieve their goal of maintaining a monopoly in the relevant market.

109. Counterclaim Defendants' market share in the relevant market, coupled with other market structure and conduct evidence, including, but not limited to, the lack of competition for filgrastim, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and related economic and market factors, constitute a dangerous probability that Counterclaim Defendants will succeed in their efforts to maintain a monopoly in the relevant market.

110. But for Counterclaim Defendants' actions alleged herein, Counterclaim Defendants' market share in the relevant market would have decreased with the addition of strong competitors, such as Apotex and other subsequent generic drug manufacturers, to the benefit of competition and consumers in the relevant market.

111. Upon information and belief, Counterclaim Defendants have not acted to advance their position by competing on the merits in the relevant market, but solely to exclude potential

competition from an alternate source in the relevant market.

112. Counterclaim Defendants' exclusionary, anticompetitive, and unlawful actions have harmed consumers by depriving them of timely market entry of low cost, alternative filgrastim biosimilar products.

113. Counterclaim Defendants have unlawfully acquired and/or maintained monopoly power in the relevant market as a result of the conduct alleged herein.

114. As demonstrated by the foregoing conduct alleged herein, Counterclaim Defendants have acted with the specific intent to monopolize the relevant market.

115. The effect of Counterclaim Defendants' overall scheme, course of conduct, and attempt to maintain a monopoly will be to unreasonably restrain trade and commerce in the relevant market, and permit Counterclaim Defendants to continue to monopolize the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

116. Counterclaim Defendants' exclusionary, anticompetitive, and unlawful activities, as alleged herein, threaten loss or damage to Apotex by forestalling, frustrating, and preventing Apotex's ability to compete in the relevant market.

117. As a result of Counterclaim Defendants' exclusionary, anticompetitive, and unlawful actions, Apotex has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities.

118. The Counterclaim Defendants are not entitled to *Noerr-Pennington* immunity in connection with their filing and maintenance of this sham lawsuit.

COUNT VI
(Declaratory Judgment of Unenforceability of the '138 Patent for Patent Misuse)

119. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and ¶¶ 1-118 of these Counterclaims.

120. Upon information and belief, Counterclaim Defendants did not carry out a good faith investigation based on the aBLA documents produced by Apotex on March 4, 2015, and the Detailed Statement provided by Apotex on June 29, 2015, and Counterclaim Defendants do not have a good faith factual or legal basis to allege that Apotex's Filgrastim Product infringes any valid and/or enforceable claim of the '138 patent.

121. Counterclaim Defendants filed this action without regard for the merits of their infringement claims and for the purpose of delaying Apotex's entry into the marketplace for filgrastim.

122. By filing and prosecuting this action, Counterclaim Defendants misused the '138 patent to obtain market benefit beyond that which inheres in the statutory patent right.

123. Counterclaim Defendants' baseless allegations of patent coverage beyond that which is actually and validly claimed impermissibly broadened the physical or temporal scope of the '138 patent.

124. Upon information and belief, Counterclaim Defendants' misuse of the '138 patent hinders and/or prevents the entry of competitors in the relevant market, and, therefore, is one in a manner that has anticompetitive effects.

125. The claims of the '138 patent are unenforceable as a result of Counterclaim Defendants' patent misuse.

COUNT VII
(Declaratory Judgment of Unenforceability of the '427 Patent for Patent Misuse)

126. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and ¶¶ 1-125 of these Counterclaims.

127. Upon information and belief, Counterclaim Defendants did not carry out a good faith investigation based on the aBLA documents produced by Apotex on March 4, 2015, and the

Detailed Statement provided by Apotex on June 29, 2015, and Counterclaim Defendants do not have a good faith factual or legal basis to allege that Apotex's Filgrastim Product infringes any valid and/or enforceable claim of the '427 patent.

128. Counterclaim Defendants filed this action without regard for the merits of their infringement claims and for the purpose of delaying Apotex's entry into the marketplace for filgrastim.

129. By filing and prosecuting this action, Counterclaim Defendants misused the '427 patent to obtain market benefit beyond that which inheres in the statutory patent right.

130. Counterclaim Defendants' baseless allegations of patent coverage beyond that which is actually and validly claimed impermissibly broadened the physical or temporal scope of the '427 patent.

131. Upon information and belief, Counterclaim Defendants' misuse of the '427 patent hinders and/or prevents the entry of competitors in the relevant market, and, therefore, is one in a manner that has anticompetitive effects.

132. The claims of the '427 patent are unenforceable as a result of Counterclaim Defendants' patent misuse.

COUNT VII
(Declaratory Judgment That Subsection (k) Applicants Who Have Complied with 42 U.S.C. § 262(*l*)(2)(A) May Elect Not to Provide Notice of Commercial Marketing to the Reference Product Sponsor, Subject to the Consequences Set Forth in 42 U.S.C. § 262(*l*)(9)(B))

133. Apotex hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and ¶¶ 1-132 of these Counterclaims.

134. In addition to providing an abbreviated pathway for regulatory approval of biosimilars, as discussed above, and providing a framework for handling patent disputes, the BPCIA also states at 42 U.S.C. § 262(l)(8)(A): "[t]he 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)."

135. In the event that a subsection (k) applicant elects not to provide a provide a notice of commercial marketing, 42 U.S.C. § 262(*l*)(9)(B) dictates the consequences:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(Emphasis added.) In other words, the BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a notice of commercial marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (*l*)(9)(B).

136. Accordingly, with regard to the notice of commercial marketing, the BPCIA contemplates at least two pathways for a biosimilar applicant who has complied with 42 U.S.C. § 262(*l*)(2)(A)—either such biosimilar applicant provides the reference product sponsor with the notice of commercial marketing or it does not.

137. Apotex is entitled to a judgment declaring that the BPCIA allows a biosimilar applicant, who has complied with 42 U.S.C. § 262(*l*)(2)(A), to elect not to provide the reference product sponsor with the notice of commercial marketing, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(B).

138. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VIII
(Declaratory Judgment of No Injunctive Relief Under BPCIA)

139. Apotex hereby incorporates by reference each and every allegation set forth in its

Answer and Affirmative Defenses to the Complaint and ¶¶ 1-138 of these Counterclaims.

140. With regard to the notice of commercial marketing, the BPCIA contemplates at least two pathways for a biosimilar applicant who has complied with 42 U.S.C. § 262(*l*)(2)(A)—either the biosimilar applicant provides the reference product sponsor with the notice of commercial marketing, or it does not.

141. The BPCIA expressly states that if the if the biosimilar applicant elects not to provide a notice of commercial marketing "the reference product sponsor . . . may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A)." 42 U.S.C. § 262(*l*)(9)(B).

142. The BPCIA does not provide for the reference product sponsor to obtain an injunction if the biosimilar applicant elects not to provide a notice of commercial marketing.

143. Apotex is entitled to a judgment declaring that Counterclaim Defendants cannot obtain injunctive relief, including enjoining Apotex 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), for Apotex electing not to provide Amgen with a notice of commercial marketing.

144. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully prays that the Court enter judgment in its favor and against Counterclaim Defendants as follows:

A. Declaring that the claims of the '138 and '427 patents are not and will not be infringed by Apotex;

B. Declaring that the claims of the ’138 and ’427 patents are invalid;

C. Declaring that the claims of the ’138 and ’427 patents are unenforceable for patent misuse;

D. Declaring that Counterclaim Defendants violated Section 2 of the Sherman Act and awarding Apotex damages (including costs and reasonable attorneys’ fees) and that such damages be trebled;

E. Declaring that Apotex may elect not to provide the reference product sponsor with a notice of commercial marketing, subject only to the consequences of 42 U.S.C. § 262(*l*)(9)(B);

F. Declaring that Counterclaim Defendants cannot obtain injunctive relief, including enjoining Apotex 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), for Apotex electing not to provide the reference product sponsor with the notice of commercial marketing;

G. Granting Apotex judgment in its favor on Plaintiffs’ Complaint;

H. Denying any and all requests by Counterclaim Defendants for injunctive relief;

I. Dismissing Plaintiffs’ Complaint with prejudice;

J. A finding that this is an exceptional case, and an award of attorneys’ fees to Apotex in this action pursuant to 35 U.S.C. § 285; and

K. Awarding Apotex any other such relief as it just and proper.

December 1, 2015

Respectfully submitted

By: */s/ Simeon D. Brier*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing **DEFENDANTS APOTEX INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT** was served by email, on December 1, 2015, on all counsel or parties of record on the service list.

/s/ Simeon D. Brier

Simeon D. Brier

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