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.	15-61631-CIV-COHN (consolidated with 15-62081-CIV-COHN)

PLAINTIFFS AMGEN INC. AND AMGEN MANUFACTURING LIMITED'S ANSWER AND AFFIRMATIVE DEFENSES TO DEFENDANTS' COUNTERCLAIMS

In response to the Counterclaims [D.E. 64] asserted by Defendants Apotex Inc. and Apotex Corp. (together, "Apotex"), Plaintiffs Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") answer as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Amgen denies all allegations in Defendants' Counterclaims except those specifically admitted below.

THE PARTIES

1. Upon information and belief, Amgen 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.

2. Upon information and belief, Amgen admits that 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. Admitted.

4. Admitted.

JURISDICTION AND VENUE

5. Amgen admits that Apotex's Counterclaims purport to 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. Amgen denies any remaining allegations of Paragraph 5.

6. Amgen admits that this Court has subject matter jurisdiction over Apotex's Counterclaims under 28 U.S.C. §§ 1331, 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(*l*). Amgen denies any remaining allegations of Paragraph 6.

7. For the purposes of this action, Amgen admits the allegations of Paragraph 7.

8. For the purposes of this action, Amgen admits the allegations of Paragraph 8.

BACKGROUND

Counterclaim Defendants and Biologics[1]

9. Amgen admits the allegations of Paragraph 9.

10. Admitted.

11. Paragraph 11 contains legal conclusions and allegations to which no answer is required.

12. Paragraph 12 contains legal conclusions and allegations to which no answer is required.

[1] Headings in Amgen's Answer and Affirmative Defenses to Apotex's Counterclaims are used solely to mirror the headings in Apotex's pleading and should not be construed as an admission or denial by Amgen on any issue.

13. Admitted.

14. Amgen admits that its Neupogen® product has been on the market in the United States for more than 12 years. The remaining allegations of Paragraph 14 are denied.

15. Admitted.

16. The content of the FDA label for Neupogen® speaks for itself. Amgen denies any remaining allegations of Paragraph 16.

17. The content of the FDA label for Neupogen® speaks for itself. Amgen denies any remaining allegations of Paragraph 17.

18. The content of the FDA label for Neupogen® speaks for itself. Amgen denies any remaining allegations of Paragraph 18.

19. Amgen admits that page 45 of Amgen Inc.'s 10-K Annual Report for the fiscal year ending December 31, 2014 states that total Neupogen® sales in the United States was $839 million. Amgen denies any remaining allegations of Paragraph 19.

Apotex and Biosimilars

20. Upon information and belief, Amgen admits the allegations of Paragraph 20.

21. Admitted.

22. Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

23. Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Amgen admits that Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) states that "[i]t is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." Amgen denies any remaining allegations of Paragraph 23.

24. Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Amgen admits that the BPCIA creates an abbreviated approval pathway for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). By following the provisions of the BPCIA, biosimilar applicants may make use of the FDA's prior determinations as to the safety, purity, and potency of the reference product that was already approved by the FDA. Under the BPCIA, the FDA reviews the biosimilar application to determine if the information submitted is sufficient to show that the biological product is "biosimilar" to the reference product—i.e. (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(k)(3)(A), (i)(2).

25. Amgen admits that Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) states that "[i]t is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." Amgen denies any remaining allegations of Paragraph 25.

26. Denied.

27. Denied.

28. Upon information and belief, Amgen admits the allegations of Paragraph 28.

The Patents-In-Suit

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

29. Admitted.

30. Admitted.

31. Amgen admits that claim 1 of the '138 patent reads:

> 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 and one or more of:
> (i) a denaturant;
> (ii) an aggregation suppressor; and
> (iii) a protein stabilizer;
> to form a refold mixture;
> (b) incubating the refold mixture; and
> (c) isolating the protein from the refold mixture.

32. Denied.

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

33. Admitted.

34. Amgen admits that the '427 Patent is entitled "Combination of G-CSF with a Chemotherapeutic Agent for Stem Cell Mobilization" and was issued on December 19, 2000.

35. Admitted.

36. Amgen admits that claim 1 of the '427 patent reads:

> A method of treating a disease requiring peripheral stem cell transplantation in a patient in need of such treatment, comprising administering to the patient a hematopoietic stem cell mobilizing-effective amount of G-CSF; and thereafter administering to the patient a disease treating-effective amount of at least one chemotherapeutic agent.

Amgen denies any remaining allegations of Paragraph 36.

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

37. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-36 as if fully set forth herein.

38. Admitted.

39. Amgen admits that Paragraph 39 states that "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)," but denies the veracity and merit of these assertions.

40. Amgen admits that claim 1 of the '138 patent reads:

> 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 and one or more of:
> (i) a denaturant;
> (ii) an aggregation suppressor; and
> (iii) a protein stabilizer;
> to form a refold mixture;
> (b) incubating the refold mixture; and
> (c) isolating the protein from the refold mixture.

Amgen otherwise denies the allegations of Paragraph 40.

41. Upon information and belief Amgen denies the 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, the allegations are denied upon information and belief.

43. Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied upon information and belief.

44. Admitted.

45. Denied.

46. Denied.

47. Admitted that this is an exceptional case such that an award to Amgen of its attorneys' fees and costs pursuant to 35 U.S.C. § 285 is justified. Denied that Apotex is entitled to an award of attorneys' fees.

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

48. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-47 as if fully set forth herein.

49. Admitted.

50. Amgen admits that Paragraph 50 states that "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," but denies the veracity and merit of these allegations.

51. Amgen admits that there is an actual, substantial, and continuing justiciable case or controversy with respect to the validity of the '138 patent.

52. Denied.

53. Denied.

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

54. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-53 as if fully set forth herein.

55. Amgen admits that Paragraph 55 states that "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)," but denies the veracity and merit of these assertions.

56. Amgen admits that claim 1 of the '427 patent reads:

> A method of treating a disease requiring peripheral stem cell transplantation in a patient in need of such treatment, comprising administering to the patient a hematopoietic stem cell mobilizing-effective amount of G-CSF; and thereafter administering to the patient a disease treating-effective amount of at least one chemotherapeutic agent.

Amgen otherwise denies the allegations of Paragraph 56.

57. Upon information and belief Amgen denies the allegations of Paragraph 57.

58. Upon information and belief Amgen denies the allegations of Paragraph 58.

Upon information and belief, FDA has not yet determined the approved indications for Apotex's Filgrastim Product.

59. Upon information and belief Amgen denies the allegations of Paragraph 59.

Upon information and belief, FDA has not yet determined the approved indications for Apotex's Filgrastim Product nor has FDA approved the proposed label for Apotex's Filgrastim Product.

60. Admitted.

61. Denied.

62. Denied.

63. Admitted that this is an exceptional case such that an award to Amgen of its attorneys' fees and costs pursuant to 35 U.S.C. § 285 is justified. Denied that Apotex is entitled to an award of attorneys' fees.

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

64. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-63 as if fully set forth herein.

65. Amgen admits that Paragraph 65 states that "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," but denies the veracity and merit of these allegations.

66. Amgen admits that there is an actual, substantial, and continuing justiciable case or controversy with respect to the validity of the '427 patent.

67. Denied.

68. Denied.

COUNT V

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

69. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-68 as if fully set forth herein.

70. Amgen admits that Apotex purports to assert a claim arising under the statutory sections cited but denies the veracity and merits of the allegations.

The Relevant Market and Counterclaim Defendants' Monopoly Power

71. Admitted.

72. Upon information and belief, Amgen admits that Apotex is engaged in the development, commercialization, and marketing of generic pharmaceutical products, including biosimilars, for the treatment of various disorders.

73. Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

74. Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

75. Upon information and belief, Amgen admits that it is one of three entities in the United States marketing a FDA-approved filgrastim product. Amgen denies any remaining allegations of Paragraph 75.

76. Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

77. Amgen admits that page 45 of Amgen Inc.'s 10-K Annual Report for the fiscal year ending December 31, 2014 states that total Neupogen® sales in the United States was $839 million. Amgen denies any remaining allegations of Paragraph 77.

78. Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

79. Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

80. Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

Apotex's Efforts to Compete with Counterclaim Defendants

81. Upon information and belief Amgen admits the allegations of Paragraph 81.

82. Amgen admits that, if approved, Apotex's Filgrastim Product will compete with Amgen's Neupogen® product. Amgen denies all remaining allegations of Paragraph 82.

83. Upon information and belief, Amgen admits that, on February 13, 2015, Apotex received notification from the FDA that their BLA had been accepted for review.

84. Admitted that Apotex provided Amgen with a copy of its aBLA No. 761027 regarding Apotex's Filgrastim Product as filed with the FDA on March 4, 2015. All remaining allegations in paragraph 84 are denied.

85. Admitted.

86. Amgen admits that, on June 29, 2015, Apotex provided Amgen with its statements designated as being in accordance with 42 U.S.C. § 262(*l*)(3)(B). All remaining allegations of Paragraph 86 are denied.

87. Amgen admits that Apotex's June 29, 2015 letter purported to provide the factual and legal bases for its contention that the claims of the '138 patent are invalid and/or will not be infringed by the commercial marketing of Apotex's Filgrastim product but denies the veracity or merits of these allegations. Amgen further denies that Apotex's June 29, 2015 letter contended that the '138 patent is unenforceable or provided any factual or legal bases for such a contention. Amgen admits that Apotex's June 29, 2015 letter purported to provide the factual and legal bases for its contention that the claims of the '427 patent will not be infringed by the commercial marketing of Apotex's Filgrastim product but denies the veracity or merits of these allegations. Amgen further denies that Apotex's June 29, 2015 letter contended that the '427 patent is invalid and/or unenforceable or provided any factual or legal bases for such contentions.

88. Amgen admits that Apotex's June 29, 2015 letter alleged that, if certain limitations were construed to refer to the refold buffer, then Apotex's manufacture of its Filgrastim Product would not fall within the claims. Amgen denies the veracity or merits of the allegations.

89. Amgen admits that Apotex's June 29, 2015 letter alleged that the commercial marketing of Apotex's Filgrastim Product will not infringe the '427 patent. Amgen denies the veracity or merits of the allegations.

90. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '138 and '427 patents shall be the subjects of an action for patent

infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '138 and '427 patents despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

Nature of Counterclaim Defendants Anticompetitive Activity

91. Denied.

92. Denied.

93. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '138 and '427 patents shall be the subjects of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '138 and '427 patents despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

94. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '138 and '427 patents shall be the subjects of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '138 and '427 patents despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

95. Denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the ’138 and ’427 patents shall be the subjects of an action for patent infringement. (Apotex’s Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the ’138 and ’427 patents despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

100. Amgen admits that, as a matter of chronology, Amgen initiated this action after Apotex provided its aBLA to Amgen. The remaining allegations of Paragraph 100 are denied.

101. Amgen admits that, as a matter of chronology, Amgen initiated this action after Apotex provided its June 29, 2015 letter (the “Detailed Statement”). The remaining allegations of Paragraph 101 are denied. Amgen “initiated litigation” after “Amgen and Apotex reached agreement that should Amgen sue, the ’138 patent and the ’427 patent would be the subject [sic] of an action for patent infringement under 42 U.S.C. § 262(*l*)(6)(A).” (Apotex’s Answer ¶ 50.) Amgen further denies that Apotex’s Detailed Statement provides any factual or legal bases for Apotex’s position on the invalidity of the ’427 patent.

102. Denied.

103. Denied.

104. Admitted that page 27 of Amgen’s 10-K Annual Report for the fiscal year ending December 31, 2014 states:

> While we are unable to predict the precise impact of the pending introduction of biosimilars on our products, we expect in the future 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.

All remaining allegations of Paragraph 104 are denied.

105. Denied.

106. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the ’138 and ’427 patents shall be the subjects of an action for patent infringement. (Apotex’s Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the ’138 and ’427 patents despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

107. Denied.

108. Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

109. Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

110. Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

111. Denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

118. Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

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

119. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-118 as if fully set forth herein.

120. Denied. Moreover, this action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '138 patent shall be the subject of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '138 patent despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

121. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '138 patent shall be the subject of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '138 patent despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

122. Denied.

123. Denied.

124. Denied.

125. Denied.

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

126. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-125 as if fully set forth herein.

127. Denied. Moreover, this action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith

negotiations with Amgen and, ultimately, agreed that the '427 patent shall be the subject of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '427 patent despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

128. Denied. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '427 patent shall be the subject of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '427 patent despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

129. Denied.

130. Denied.

131. Denied.

132. Denied.

COUNT VIII [Formerly Count VII][2]
(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. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-132 as if fully set forth herein.

134. Admitted.

135. Amgen admits that 42 U.S.C. § 262(*l*)(9)(B) provides as follows:

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

[2] Amgen notes that Apotex's Counterclaims contained two counts labeled "Count VII." In responding herein, Amgen renumbers Apotex's numbering scheme to consider this "Count VIII."

> declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

Amgen denies the remaining allegations of Paragraph 135. Amgen specifically denies that § 262(*l*)(9)(B) permits a biosimilar applicant to "elect[ ] not to provide a provide [sic] a notice of commercial marketing."

136. Denied.

137. Denied.

138. Denied.

COUNT IX [Formerly Count VIII]
(Declaratory Judgment of No Injunctive Relief Under BPCIA)

139. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-138 as if fully set forth herein.

140. Denied.

141. Amgen admits that 42 U.S.C. § 262(*l*)(9)(B) provides as follows:

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

Amgen denies the remaining allegations of Paragraph 141. Amgen specifically denies that § 262(*l*)(9)(B) permits a biosimilar applicant to "elect[ ] not to provide a notice of commercial marketing."

142. Denied.

143. Denied.

144. Denied.

PRAYER FOR RELIEF

Amgen denies that Apotex is entitled to judgment or any of the relief requested by the Counterclaims, including that requested in Paragraphs A through K of the Counterclaims.

AFFIRMATIVE DEFENSES

By characterizing these as "Affirmative Defenses," as Apotex does in its Answer, Amgen is not taking on any burden of proof beyond that which the law applies to it. Thus, without admitting or implying that Amgen bears the burden of proof as to any of them, Amgen, on information and belief, asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

1. Apotex's Counterclaims VIII and IX [formerly VII and VIII] fail to state a claim for which relief can be granted because they are merely defenses directed at an element of Amgen's claims, and are not proper counterclaims.

SECOND AFFIRMATIVE DEFENSE
(Failure to State a Claim)

2. Apotex's Counterclaims VI and VII fail to state a claim for which relief can be granted. Apotex failed to state claims for patent misuse; Counterclaims VI and VII contain mere assertions of non-infringement.

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim)

3. Apotex's Counterclaim V fails to state a claim for which relief can be granted.

FOURTH AFFIRMATIVE DEFENSE
(Waiver)

4. Because Apotex failed to assert any bases for the unenforceability of the '138 patent or the '427 patent in its Detailed Statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Apotex waived any claim or defense grounded in unenforceability.

FIFTH AFFIRMATIVE DEFENSE
(Waiver)

5. Because Apotex failed to assert any basis for the invalidity of the '427 patent in its Detailed Statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Apotex waived any claim or defense grounded in invalidity of the '427 patent.

SIXTH AFFIRMATIVE DEFENSE
(Estoppel)

6. Because Apotex failed to assert any bases for the unenforceability of the '138 patent or the '427 patent in its Detailed Statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Apotex should be estopped from asserting the unenforceability of the '138 and '427 patents.

SEVENTH AFFIRMATIVE DEFENSE
(Estoppel)

7. Because Apotex failed to assert any basis for the invalidity of the '427 patent in its Detailed Statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Apotex should be estopped from asserting the invalidity of the '427 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Estoppel)

8. Apotex should be estopped from claiming that this action is a sham litigation and/or that this action is baseless. This action was commenced pursuant to 42 U.S.C. § 262(*l*)(4)(A) and (6)(A), after Apotex—by its own admission—engaged in good-faith negotiations with Amgen and, ultimately, agreed that the '138 and '427 patents shall be the subjects of an action for patent infringement. (Apotex's Answer ¶¶ 12, 50.) Apotex agreed to the inclusion of the '138 and '427 patents despite having a statutorily permitted option not to agree. *See* 42 U.S.C. § 262(*l*)(4)(B), (5).

Dated: December 23, 2015

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Amgen Inc. and Amgen Manufacturing Limited

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 23, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel and that a true and correct copy was served via electronic mail on all counsel of parties of record.

By: */s/ John F. O'Sullivan*_____
John F. O'Sullivan
Fla. Bar No. 143154