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

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendant.	Case No. 15-cv-61631-CIV-JIC/BSS

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

In response to the Counterclaims 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. Upon information and belief, 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 Neulasta® product has been on the market in the United States for more than 12 years. The remaining allegations of Paragraph 14 are denied.

15. Amgen admits that Neulasta® is approved as indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

16. Amgen admits that page 45 of Amgen Inc.'s 10-K Annual Report for the fiscal year ending December 31, 2014 states that total Neulasta® sales in the United States was $3,649 million. Amgen denies any remaining allegations of Paragraph 16.

Apotex and Biosimilars

17. Upon information and belief, Amgen admits the allegations of Paragraph 17.

18. Admitted.

19. Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

20. Paragraph 20 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 20.

21. Paragraph 21 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).

22. 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."

23. Denied.

24. Denied.

25. Upon information and belief, Amgen admits the allegations of Paragraph 25.

The Patents-In-Suit

U.S. Patent No. 5,824,784

26. Admitted.

27. Admitted.

28. Admitted.

29. Amgen admits that, on April 17, 2015, Apotex informed Amgen that it did not intend to begin commercial marketing of its Pegfilgrastim Product before the date that the '784 patent expires. Any remaining allegations of Paragraph 29 are denied.

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

30. Admitted.

31. Admitted.

32. 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.

33. Denied.

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

34. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-33 as if fully set forth herein.

35. Admitted.

36. Amgen admits that Paragraph 36 states that "Apotex asserts that the manufacture, use, offer for sale, sale, or importation of Apotex's Pegfilgrastim 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.

37. 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 37.

38. Upon information and belief Amgen denies the allegations of Paragraph 38.

39. Upon information and belief Amgen denies the allegations of Paragraph 39.

40. Upon information and belief Amgen denies the allegations of Paragraph 40.

41. Admitted.

42. Denied.

43. Denied.

44. 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)

45. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-44 as if fully set forth herein.

46. Admitted.

47. Amgen admits that Paragraph 47 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.

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

49. Denied.

50. Denied.

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

51. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-50 as if fully set forth herein.

52. 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

53. Admitted.

54. 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.

55. Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

56. Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

57. Upon information and belief, Amgen admits that it is currently the only entity in the United States lawfully marketing a FDA-approved pegfilgrastim product. Amgen denies any 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, the allegations are denied.

59. Amgen admits that page 45 of Amgen Inc.'s 10-K Annual Report for the fiscal year ending December 31, 2014 states that total Neulasta® sales in the United States was $3,649 million. Amgen denies any remaining allegations of Paragraph 59.

60. Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

61. Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

62. Paragraph 62 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

63. Upon information and belief Amgen admits the allegations of Paragraph 63.

64. Amgen admits that, if approved, Apotex's Pegfilgrastim Product will compete with Amgen's Neulasta® product. Amgen denies all remaining allegations of Paragraph 64.

65. Upon information and belief, Amgen admits that, on December 15, 2014, Apotex received notification from the FDA that their BLA had been accepted for review.

66. Admitted that Apotex provided Amgen with a copy of its BLA No. 761026 regarding Apotex's Pegfilgrastim Product as filed with the FDA on October 16, 2014. All remaining allegations in paragraph 66 are denied.

67. Admitted.

68. Amgen admits that, on April 17, 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 68 are denied.

69. Amgen admits that Apotex's April 17, 2015 letter contained a statement that, pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II), Apotex did not intend to begin commercial marketing of its Pegfilgrastim Product before the expiration date of the '784 and '933 patents. All remaining allegations of Paragraph 69 are denied.

70. Amgen admits that Apotex's April 17, 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 Pegfilgrastim product but denies the veracity or merits of these allegations. Amgen further denies that Apotex's April 17, 2015 letter contended that the '138 patent is unenforceable or provided any factual or legal bases for such a contention.

71. Amgen admits that Apotex's April 17, 2015 letter alleged that, if certain limitations were construed to refer to the refold buffer, then Apotex's manufacture of its Pegfilgrastim Product would not fall within the claims. Amgen denies the veracity or merits of the allegations.

72. 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, 51.) 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).

Nature of Counterclaim Defendants Anticompetitive Activity

73. Denied.

74. Denied.

75. 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, 51.) 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).

76. 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, 51.) 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).

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. 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, 51.) 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).

82. Denied.

83. Amgen admits that, as a matter of chronology, Amgen initiated this action after Apotex provided its April 17, 2015 letter (the "Detailed Statement"). The remaining allegations of Paragraph 83 are denied. Amgen "initiated litigation" after "Amgen and Apotex reached

agreement that should Amgen sue, the '138 patent and the '784 patent would be the subject [sic] of an action for patent infringement under 42 U.S.C. § 262(*l*)(6)(A)." (Apotex's Answer ¶ 51.)

84. Denied.

85. Denied.

86. 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 86 are denied.

87. Denied.

88. 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, 51.) 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).

89. Denied.

90. Paragraph 90 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

91. Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

92. Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations are denied.

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

101. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-100 as if fully set forth herein.

102. 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, 51.) 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).

103. 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, 51.) 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).

104. Denied.

105. Denied.

106. Denied.

107. Denied.

COUNT V
(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))

108. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-107 as if fully set forth herein.

109. Admitted.

110. 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 110. 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."

111. Denied.

112. Denied.

113. Denied.

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

114. Amgen incorporates by reference its answers to the allegations of Paragraphs 1-113 as if fully set forth herein.

115. Denied.

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

117. Denied.

118. Denied.

119. 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 V and VI 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 Counterclaim IV fails to state a claim for which relief can be granted. Apotex failed to state a claim for patent misuse; Counterclaim IV contains mere assertions of non-infringement.

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

FOURTH AFFIRMATIVE DEFENSE
(Waiver)

4. Because Apotex failed to assert any basis for the unenforceability of the '138 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
(Estoppel)

5. Because Apotex failed to assert any basis for the unenforceability of the '138 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 patent.

SIXTH AFFIRMATIVE DEFENSE
(Estoppel)

6. 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 patent shall be the subject of an action for patent infringement. (Apotex's Answer ¶¶ 12, 51.) 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).

Dated: October 29, 2015

By: */s/ John F. O'Sullivan*
John F. O'Sullivan
Fla. Bar No. 143154
Allen P. Pegg
Fla. Bar No. 597821
HOGAN LOVELLS US LLP
600 Brickell Ave., Suite 2700
Miami, FL 33131
Telephone: (305) 459-6500
Facsimile: (305) 459-6550
john.osullivan@hoganlovells.com
allen.pegg@hoganlovells.com

Of Counsel:

Nicholas Groombridge
Catherine Nyarady
Eric Alan Stone
Jennifer Gordon
Peter Sandel
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
estone@paulweiss.com
jengordon@paulweiss.com
psandel@paulweiss.com

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com
loisk@amgen.com
kmorley@amgen.com

Attorneys for Plaintiffs
Amgen Inc. and Amgen Manufacturing Limited

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 29, 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