IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 16-666-SLR
AMGEN INC. and AMGEN MANUFACTURING LTD.,	)	
Defendants.	)	

ABBVIE INC. AND ABBVIE BIOTECHNOLOGY LTD.'S
ANSWER AND DEFENSES TO AMGEN INC.
AND AMGEN MANUFACTURING LTD.'S COUNTERCLAIMS

Plaintiffs AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, "AbbVie" or "Plaintiffs") hereby respond to the numbered allegations in the Counterclaims and Answer of Defendants Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen" or "Defendants"), and set forth their affirmative defenses thereto. To the extent that the headings or other non-numbered statements in Amgen's Counterclaims and Answer contain any allegations, AbbVie denies each and every allegation therein. This pleading is based upon AbbVie's knowledge as to its own activities, and upon information and belief as to the activities of others.

Except as specifically admitted below, AbbVie denies the allegations of Amgen's Counterclaims and Answer. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. AbbVie denies that Amgen is entitled to the relief requested or to any other relief.

More specifically, subject to and notwithstanding these objections, AbbVie responds as follows:

PARTIES

1. On information and belief, AbbVie admits the allegations of Paragraph 1.

2. On information and belief, AbbVie admits the allegations of Paragraph 2.

3. On information and belief, AbbVie admits that Amgen Manufacturing Ltd. is a subsidiary of Amgen Inc. and that it participates in the manufacture of medications marketed by Amgen Inc. and its subsidiaries. AbbVie is without sufficient knowledge and information to form a belief as to the truth of the remaining allegations of paragraph 3 and therefore denies the same.

4. AbbVie is without sufficient knowledge and information to form a belief as to the truth of the allegations of paragraph 4 and therefore denies the same.

5. AbbVie is without sufficient knowledge and information to form a belief as to the truth of the allegations of paragraph 5 and therefore denies the same.

6. Admitted.

7. Admitted.

JURISDICTION AND VENUE

8. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that Amgen's Counterclaims purport to bring an action that arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 et seq. AbbVie admits that Amgen's Counterclaims purport to bring an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. AbbVie denies the remaining allegations of paragraph 8.

9. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie does not contest that venue is proper in this Court for purposes of this case.

10. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie does not contest personal jurisdiction in this Court for purposes of this case.

The BPCIA

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA") in 2010 and that the BPCIA defines biosimilar to be a biologic product that: (1) is "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 safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2)(A), (B). AbbVie denies the remaining allegations of paragraph 11.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that the BPCIA sets forth procedures for the subsection (k) applicant and reference product sponsor to exchange information and contentions, and for the subsection (k) applicant to provide notice of commercial marketing. AbbVie denies the remaining allegations of paragraph 12.

AbbVie's Compliance and Amgen's Non-Compliance with the BPCIA

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie denies that Amgen has fully complied with its obligations under the BPCIA. Despite the clear mandate of the BPCIA and repeated entreaties by AbbVie, Amgen refused to engage in good faith negotiations over which patents should be the subject of this litigation. *See* 42 U.S.C. § 262(*l*)(4)(A). AbbVie denies the remaining allegations of paragraph 13.

14. AbbVie admits that on January 25, 2016, Amgen informed AbbVie that the FDA had accepted its abbreviated Biologics License Application ("aBLA") for review. AbbVie is without sufficient knowledge and information to form a belief as to the truth of the remaining allegations of paragraph 14, but understands that Amgen has stated that it submitted its abbreviated Biologics License Application (BLA No. 761024) to the FDA on November 25, 2015 seeking a license to market a biosimilar version of AbbVie's HUMIRA® (adalimumab)

product. AbbVie denies the remaining allegations of paragraph 14.

15. AbbVie admits that on February 10, 2016, Amgen provided AbbVie a copy of its aBLA under the confidentiality provisions set forth in 42 U.S.C. § 262(*l*)(1) of the BPCIA. AbbVie admits that Amgen's aBLA contains information concerning ABP 501, including some information describing the processes used to manufacture ABP 501. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 15.

42 U.S.C. § 262(*l*)(3) Information Exchange

16. AbbVie admits that on April 11, 2016, pursuant to 42 U.S.C. § 262(*l*)(3)(A), AbbVie provided Amgen with a list of patents (and allowed patent applications) for which it believed a claim of patent infringement could be reasonably asserted against Amgen's adalimumab biosimilar ("3(A) List"). AbbVie admits that this list identified 61 patents and 5 allowed patent applications (which have since granted, and which the parties agreed to treat the same as the allowed patents on the 3(A) List). AbbVie admits that on June 22, 2016, pursuant to 42 U.S.C. § 262(*l*)(7), AbbVie provided a supplemental patent list adding a recently issued patent. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 16.

17. AbbVie admits that on June 10, 2016, Amgen provided AbbVie with a statement contesting Amgen's infringement and/or the validity of 65 of the patents on AbbVie's 3A List ("3(B) Statement"). AbbVie admits that, as to the remaining patent not included in Amgen's 3(B) Statement, Amgen represented that it does not intend to begin commercial marketing of ABP 501 before that patent expires on December 31, 2016. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 17.

18. AbbVie admits that Amgen's 3(B) Statement totaled over 2,750 pages. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 18.

19. AbbVie admits that, despite AbbVie's requests, Amgen did not provide any additional evidence (e.g., additional manufacturing documents or product information, beyond what was in the aBLA) relating to its contentions. AbbVie denies that Amgen clearly identified each of the publicly available invalidity references on which it relied. Except as admitted herein,

AbbVie denies the remaining allegations of paragraph 19.

20. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that 42 U.S.C. § 262(*l*)(3)(C) states that "the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." AbbVie admits the BPCIA required that AbbVie provide its 3(C) Statement to Amgen "[n]ot later than 60 days after receipt of" Amgen's 3(B) Statement, by August 9, 2016. 42 U.S.C. § 262(*l*)(3)(C) . AbbVie admits that on June 21, 2016, it provided Amgen with its 3(C) Statement. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 20.

21. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that in its 3(C) Statement, it identified 6 patents for which it was no longer pursuing an infringement claim. AbbVie admits that its 3(C) Statement did not provide infringement contentions for all claims of the 59 patents included on its 3(A) List, consistent with the Statute and Amgen's own practice in prior cases. AbbVie admits that its 3(C) Statement stated that "[s]hould AbbVie learn additional information (e.g., during discovery) that is pertinent to these patents and claims, AbbVie reserves the right to assert them and seek any and all remedies, including lost profits and injunctive relief." Except as admitted herein, AbbVie denies the remaining allegations of paragraph 21.

22. Denied.

23. Denied.

42 U.S.C. § 262(*l*)(4) Negotiations and § 262(*l*)(5) Patent Resolution Exchange

24. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that 42 U.S.C. § 262(*l)*(4)(A) states "[a]fter receipt

by the subsection (k) applicant of the statement under paragraph 3(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6)."

25. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that the BPCIA states that "[a]fter receipt by the [biosimilar] applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations . . . ." 42 U.S.C. § 262(*l*)(4)(A). AbbVie admits that on June 24, 2016, July 1, 2016, and July 15, 2016, rather than engaging in good faith negotiations to identify the patents that would be the subject of an immediate patent infringement action, as required by the BPCIA, Amgen sent letters baselessly alleging that AbbVie had not complied with paragraph (3)(C). AbbVie admits that it did not supplement its 3(C) Statement in response to these letters, because there was no need or reason to do so. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 25.

26. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that on the same day that it provided its 3(C) Statement and that negotiations were supposed to have begun under the statute, AbbVie attempted to negotiate in good faith by providing Amgen with its opening proposal that the parties "agree[] that all patents addressed in AbbVie's 3C Statement be included in the infringement action under § 262(*l*)(6)." AbbVie admits that it restated this proposal on June 30, 2016. AbbVie admits that Amgen responded on July 1, 2016, refusing to provide a counter-proposal and arguing that negotiations could not begin due to alleged deficiencies in AbbVie's 3(C) Statement. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 26.

27. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that, despite Amgen's refusal to participate in (*l*)(4) Negotiations beginning on the day AbbVie provided its 3(C) Statement, as required by the

statute, it reached an agreement with Amgen on July 7, 2016, to treat the (*l*)(4) Negotiations as if they began on July 15, 2016. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 27.

28. AbbVie admits that it repeatedly proposed, in the interests of justice, that the parties litigate "all patents addressed in AbbVie's 3C Statement," and that Amgen refused, instead proposing that AbbVie select a subset of its patents to litigate in a first suit. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 28.

29. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that the BPCIA states that if "the subsection (k) applicant and the reference product sponsor fail to agree . . . . [t]he subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I)." 42 U.S.C. § 262(*l*)(4)(B), (5)(A). AbbVie admits that the Federal Circuit has stated that the BPCIA "gives the applicant a scope-limiting ability, based on an exchange of lists of patents to be litigated" and gives the "applicant substantial authority to force such a limitation on the scope of the first-stage litigation."

30. AbbVie admits that on July 30, 2016, on the last day of the (*l*)(4) Negotiation period, Amgen notified AbbVie that it would agree to be sued on six patents. AbbVie admits that this meant that the maximum number of patents that could be part of a first lawsuit under the BPCIA was twelve (six patents from each side). Except as admitted herein, AbbVie denies the remaining allegations of paragraph 30.

31. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that the BPCIA states that "the subsection (k) applicant and the reference product sponsor shall simultaneously exchange (I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and (II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6)." 42 U.S.C. § 262(*l*)(5)(B)(i). AbbVie admits that the BPCIA states that

"the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I)." *Id.* § 262(*l*)(5)(B)(ii). AbbVie admits that both Amgen and AbbVie identified six patents, and that because two patents appeared on both parties' lists, a maximum of ten patents could be included in a first lawsuit brought under 42 U.S.C. § 262(*l*)(6).

42 U.S.C. § 262(*l*)(6) Litigation

32. Admitted.

33. AbbVie admits that Amgen's Counterclaims purport to seek a declaration that each of the ten patents asserted in AbbVie's Complaint is not infringed and/or is invalid.

42 U.S.C. § 262(*l*)(8)(A) Commercial Notice

34. AbbVie admits that, in its Complaint, it correctly stated that Amgen refused to respond to AbbVie's requests for confirmation that Amgen intends to comply with the notice requirement in the BPCIA, *see* 42 U.S.C. § 262(*l*)(8)(A). AbbVie admits that, under subparagraph (*l*)(8)(A), the "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." AbbVie is without sufficient knowledge and information to form a belief as to the truth of the remaining allegations of paragraph 34 and therefore denies the same.

35. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that on June 21, 2016, AbbVie asked that Amgen confirm by no later than June 28, 2016, that Amgen would provide AbbVie with at least 180 days' notice of commercial marketing should it receive a license from the FDA. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 35.

36. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, AbbVie admits that in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015), the Federal Circuit held that "under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its

product. AbbVie further admits that in *Amgen Inc. v. Apotex Inc*., No. 2016-1308, slip op. at 3-4 (Fed. Cir. July 5, 2016), the Federal Circuit held that "the commercial marketing provision is mandatory, with the 180-day beginning only upon post-licensure notice," even for an applicant that has complied with the information exchange procedures under paragraphs (*l*)(2) to (*l*)(6).

37. AbbVie is without sufficient knowledge and information to form a belief as to the truth of the allegations of paragraph 37 and therefore denies the same.

COUNT I

Infringement and Validity of U.S. Patent No. 8,663,945

38. AbbVie repeats and re-alleges its responses to Paragraphs 1-37 as though fully set forth herein.

39. Admitted.

40. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the '945 Patent, including claims 1-5, 7, 9-16, 18, 20-27, 29, and 31-39. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 40.

41. Denied.

42. Denied.

43. Denied.

COUNT II

Infringement and Validity of U.S. Patent No. 8,911,964

44. AbbVie repeats and re-alleges its responses to Paragraphs 1-43 as though fully set forth herein.

45. Admitted.

46. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the '964 Patent, including at least claims 1-5, 9-16, 20-21, 23-26, and 29-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 46.

47. Denied.

48. Denied.

49. Denied.

COUNT III

Infringement and Validity of U.S. Patent No. 8,916,157

50. AbbVie repeats and re-alleges its responses to Paragraphs 1-49 as though fully set forth herein.

51. Admitted.

52. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’157 Patent, including at least claims 1-7, 10-11, 15-16, and 18-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 52.

53. Denied.

54. Denied.

55. Denied.

COUNT IV

Infringement and Validity of U.S. Patent No. 8,961,973

56. AbbVie repeats and re-alleges its responses to Paragraphs 1-55 as though fully set forth herein.

57. Admitted.

58. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’973 Patent, including at least claims 1-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 58.

59. Denied.

60. Denied.

61. Denied.

COUNT V

Infringement and Validity of U.S. Patent No. 8,986,693

62. AbbVie repeats and re-alleges its responses to Paragraphs 1-61 as though fully set forth herein.

63. Admitted.

64. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’693 Patent, including at least claims 1-8. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 64.

65. Denied.

66. Denied.

67. Denied.

COUNT VI

Infringement and Validity of U.S. Patent No. 9,096,666

68. AbbVie repeats and re-alleges its responses to Paragraphs 1-67 as though fully set forth herein.

69. Admitted.

70. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’666 Patent, including at least claims 1-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 70.

71. Denied.

72. Denied.

73. Denied.

COUNT VII

Infringement and Validity of U.S. Patent No. 9,220,781

74. AbbVie repeats and re-alleges its responses to Paragraphs 1-73 as though fully set forth herein.

75. Admitted.

76. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’781 Patent, including at least claims 1-2, 4-6, 15-18, 20-22, 27, and 29-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 76.

77. Denied.

78. Denied.

79. Denied.

COUNT VIII

Infringement and Validity of U.S. Patent No. 9,272,041

80. AbbVie repeats and re-alleges its responses to Paragraphs 1-79 as though fully set forth herein.

81. Admitted.

82. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’041 Patent, including at least claims 1-2, 4-7, 16-19, 21-23, and 28-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 82.

83. Denied.

84. Denied.

85. Denied.

COUNT IX

Infringement and Validity of U.S. Patent No. 9,359,434

86. AbbVie repeats and re-alleges its responses to Paragraphs 1-85 as though fully set forth herein.

87. Admitted.

88. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the ’434 Patent, including at least claims 1-5, 7-21, and 23-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 88.

89. Denied.

90. Denied.

91. Denied.

COUNT X

Infringement and Validity of U.S. Patent No. 9,365,645

92. AbbVie repeats and re-alleges its responses to Paragraphs 1-91 as though fully set forth herein.

93. Admitted.

94. AbbVie admits that it has alleged that Amgen Inc. and Amgen Manufacturing Ltd. have infringed and will infringe the '645 Patent, including at least claims 1-7, 12-21, and 26-30. Except as admitted herein, AbbVie denies the remaining allegations of paragraph 82.

95. Denied.

96. Denied.

97. Denied.

ABBVIE'S AFFIRMATIVE DEFENSES

AbbVie asserts the following affirmative and other defenses without prejudice to its right to plead additional defenses as discovery progresses.

FIRST AFFIRMATIVE DEFENSE

Amgen's Counterclaims fail to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

AbbVie's actions in defending against Amgen's Counterclaims do not give rise to an exceptional case under 35 U.S.C. § 285.

THIRD AFFIRMATIVE DEFENSE

Amgen cannot maintain the asserted Counterclaims because it has not complied with the BPCIA.

FOURTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over Amgen's Counterclaims.

OTHER AFFIRMATIVE DEFENSES RESERVED

AbbVie reserves the right to assert further affirmative defenses in the event that discovery indicates that such would be appropriate.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests the following relief:

A. That the Court deny all the relief sought by Amgen in its Answer, Defenses, and Counterclaims;

B. That the Court dismiss with prejudice each and every one of the Counterclaims;

C. That Amgen takes nothing by its Counterclaims;

D. That the Court award AbbVie the relief sought in its Complaint;

E. That the Court award AbbVie the attorney's fees and costs incurred in this action; and

F. That the Court award such other and further relief as it may deem just and proper.

Respectfully submitted,

ROSS ARONSTAM & MORITZ LLP

/s/ Benjamin J. Schladweiler

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Dated: October 7, 2016

CERTIFICATE OF SERVICE

I, Benjamin J. Schladweiler, hereby certify that on October 7, 2016, a true copy of the foregoing ***AbbVie Inc. and AbbVie Biotechnology Ltd.'s Answer and Defenses to Amgen Inc. and Amgen Manufacturing Ltd.'s Counterclaims*** was served via electronic mail upon the following counsel of record:

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