IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD, Plaintiffs, -against- BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC., Defendants.	Civil Action No. 17-cv-01065-MSG

BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., AND BOEHRINGER INGELHEIM FREMONT, INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Boehringer Ingelheim International GmbH ("BII"), Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), and Boehringer Ingelheim Fremont, Inc. ("BIFI") (collectively, "Defendants"), by their undersigned attorneys, hereby respond to the complaint of Plaintiffs and Counterclaim-Defendants AbbVie Inc. and AbbVie Biotechnology Ltd (collectively, "Plaintiffs") as follows.

Plaintiffs' complaint defines "Boehringer" to include BII, BIPI, and BIFI, and "AbbVie" to include AbbVie Inc. and AbbVie Biotechnology Ltd. The use of these definitions in the complaint creates ambiguity and confusion with respect to certain of Plaintiffs' allegations. In their Answer, Defenses, and Counterclaims, BII, BIPI, and BIFI refer to themselves collectively as "Defendants" and to AbbVie Inc. and AbbVie Biotechnology Ltd as "Plaintiffs." All references in Defendants' Answer, Defenses, and Counterclaims to BII, BIPI, BIFI, AbbVie Inc., and AbbVie Biotechnology Ltd mean the individual defendant or plaintiff.

ANSWER AND DEFENSES

Each of the paragraphs below corresponds to the same numbered paragraph in Plaintiffs' complaint. Defendants deny all allegations in the complaint, whether express or implied, that are not specifically admitted below. Defendants further deny that Plaintiffs are entitled to the relief requested or any other relief. Any factual allegation below is admitted only as to the specific admitted facts, and not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Many of Plaintiffs' allegations in the complaint are vague and/or ambiguous, including, *inter alia*, Plaintiffs' use of the collective terms "Boehringer" and "AbbVie." To the extent any allegation in Plaintiffs' complaint is vague and/or ambiguous, Defendants deny the allegation in question.

INTRODUCTION

1. Admitted in part; denied in part. Defendants admit only that this is a purported action for patent infringement; that Plaintiffs' complaint identifies 74 patents that they allege could reasonably be asserted with respect to the adalimumab product set forth in Biologics License Application No. 761058 ("the BLA Product"); that the Biosimilar Price Competition and Innovation Act ("BPCIA") created an abbreviated regulatory pathway for approval of biosimilar versions of approved biologic products, such as Humira®; and that Plaintiffs seek (but are not entitled to) an injunction in this case. Defendants deny the remaining allegations of paragraph 1.

2. Admitted in part; denied in part. Defendants admit only that the active ingredient in Humira®, adalimumab, is a biologic drug; that biologic drugs are manufactured in living cells rather than by chemical synthesis; and that adalimumab was the first fully human antibody approved by the Food and Drug Administration ("FDA"). Defendants deny the remaining allegations of paragraph 2.

3. Admitted in part; denied in part. Defendants admit only that the approved indications for Humira® include rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis. Defendants deny the allegations of the last sentence of paragraph 3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3, and therefore deny the same.

4. Admitted in part; denied in part. Defendants admit only that Humira® contains adalimumab in a liquid formulation for subcutaneous injection. Defendants deny the remaining allegations of paragraph 4.

5. Admitted in part; denied in part. Defendants admit only that Humira® contains adalimumab, a biologic drug created in living organisms. Defendants deny the remaining allegations of paragraph 5.

6. Denied.

7. Admitted in part; denied in part. Defendants admit only that the BPCIA describes a multi-step process for the disclosure of information, the resolution or narrowing of patent disputes, and, if necessary and appropriate, the commencement of patent litigation; that from March 13, 2017, until July 26, 2017, Plaintiffs identified 74 patents that they contended could reasonably be asserted with respect to the BLA Product; that on July 26, 2017, and pursuant to 42 U.S.C. § 262(*l*)(5)(A), counsel for Defendants provided counsel for Plaintiffs with notice of the number of patents (up to five) to be selected by each side for litigation filed under 42 U.S.C. § 262(*l*)(6)(B); that on July 31, 2017, at 5 pm Eastern Time, counsel for Plaintiffs and Defendants simultaneously exchanged their respective lists of five patents pursuant to 42 U.S.C. § 262(*l*)(5)(B); and that, because two patents were identified by counsel for both Plaintiffs and

Defendants, the eight patents asserted in this litigation include all of the patents identified by both sides. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the sixth and seventh sentences of paragraph 7 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 7.

8. Admitted in part; denied in part. Defendants admit only that Plaintiffs are seeking an injunction in this litigation, to which Plaintiffs are not entitled. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the second sentence of paragraph 8 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 8.

NATURE OF THE ACTION

9. Admitted in part; denied in part. Defendants admit only that paragraph 9 of the complaint identifies AbbVie Inc. and AbbVie Biotechnology Ltd as plaintiffs in this action. Defendants deny any other allegations in paragraph 9.

10. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Defendants deny the remaining allegations of paragraph 10.

11. Denied.

12. On information and belief, admitted.

13. Admitted in part; denied in part. Defendants admit only that adalimumab is a biologic drug; that adalimumab is a fully human, high-affinity, and neutralizing therapeutic antibody to human TNF-α; and that TNF-α is a protein made by the human body as part of the body's immune response. Defendants lack sufficient knowledge or information to form a belief

as to the allegations of the first sentence of paragraph 13, and therefore deny the same. Defendants deny the remaining allegations of paragraph 13.

14. Admitted in part; denied in part. Defendants admit only that adalimumab was the first fully human antibody approved by the FDA; that adalimumab, disclosed and claimed in U.S. Patent No. 6,090,382 ("the '382 patent"), was a significant scientific achievement; and that Remicade® (infliximab) is a chimeric antibody approved for intravenous injection. Defendants lack sufficient knowledge or information to form a belief as to the allegations of the third sentence of paragraph 14, and therefore deny the same. Defendants deny the remaining allegations of paragraph 14.

15. Denied. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 15, and therefore deny the same.

16. Admitted in part; denied in part. On information and belief, Defendants admit only that Humira® (adalimumab) was one of the recipients of the Prix Galien USA in 2007. Otherwise, denied.

17. Denied. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 17, and therefore deny the same.

18. Admitted in part, denied in part. Defendants admit only that Plaintiffs' complaint identifies 74 patents that Plaintiffs allege could reasonably be asserted with respect to the BLA Product. Defendants deny the remaining allegations of paragraph 18.

19. Admitted in part; denied in part. Defendants admit only that, pursuant to the procedures set forth in the BPCIA and the circumstances described in paragraph 7 above, there are eight patents at issue in this litigation. The last sentence of paragraph 19 states legal

conclusions to which no answer is required. Defendants deny the remaining allegations of paragraph 19.

20. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, to which they are not entitled, relating to the eight patents in dispute in this case, and that the BPCIA created an abbreviated regulatory pathway for the approval of biosimilar drugs. Defendants lack sufficient knowledge or information to form a belief as to the truth of the last sentence of paragraph 20 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 20.

PARTIES

21. On information and belief, admitted.

22. On information and belief, admitted.

23. Admitted.

24. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 24.

25. Admitted.

26. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 26.

27. Admitted.

28. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any

required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 28.

29. Admitted.

30. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided, and that such activities will provide benefits, including to patients. Defendants deny the remaining allegations of paragraph 30.

JURISDICTION AND VENUE

31. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and that a justiciable case or controversy exists. Defendants deny the remaining allegations of paragraph 31.

32. Without waiver of their right to challenge the propriety of jurisdiction in other cases, Defendants do not contest this Court's exercise of personal jurisdiction over them solely for the purposes of the above-captioned action. Otherwise, denied.

33. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BIPI does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

34. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured in the United States, and that the BLA Product will be marketed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

35. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BIFI does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

36. Admitted in part; denied in part. Defendants admit only that BIFI's facilities will be used for the manufacture of biologic products, and that the sources cited in paragraph 36 include the quoted language. Otherwise, denied.

37. Admitted in part; denied in part. Defendants admit only that BIFI's facilities will be used to manufacture the BLA Product. Otherwise, denied.

38. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BII does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

39. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured in the United States, and that the BLA Product will be marketed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

40. Admitted in part; denied in part. Defendants admit only that BII has been involved in clinical studies related to the BLA Product. Otherwise, denied.

41. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

42. Denied.

43. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 43 includes the quoted language. Otherwise, denied.

44. Admitted.

45. Admitted in part; denied in part. Defendants admit only that counsel for Defendants communicated with counsel for Plaintiffs during the BPCIA exchanges. Otherwise, denied.

46. Admitted in part; denied in part. Defendants admit only that BII previously initiated certain patent infringement lawsuits in the District of Delaware that are not related to this action. Otherwise, denied.

47. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BII does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

48. Without waiver of their right to challenge the propriety of venue in other cases, Defendants do not contest venue in the District of Delaware solely for the purposes of the above-captioned action. Otherwise, denied.

THE PARTIES' EXCHANGES UNDER THE BPCIA

49. Admitted in part; denied in part. Defendants admit only the second sentence of paragraph 49 and that BIPI submitted Biologics License Application No. 761058 for the BLA Product ("BLA 761058") to the FDA on October 27, 2016. Defendants deny the remaining allegations of paragraph 49.

50. Admitted in part; denied in part. Defendants admit that Congress created an act of artificial infringement related to the submission of an application under subsection 262(k) for purposes of subject matter jurisdiction; that the BPCIA sets forth a series of pre-litigation exchanges outlined at 42 U.S.C. § 262(*l*); that 42 U.S.C. § 262(*l*)(8)(A) states, "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)"; and that 42 U.S.C. § 262(*l*)(8)(B) states that "the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement . . . ." Defendants deny the remaining allegations of paragraph 50.

51. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

52. Admitted in part; denied in part. Defendants admit only that counsel for Defendants contacted counsel for Plaintiffs on January 9, 2017, to inform Plaintiffs that BLA 761058 had been accepted by the FDA for review. Otherwise, denied.

53. Admitted in part; denied in part. Defendants admit only that the exchange of information in accordance with the procedures outlined in the BPCIA began in January 2017 and that, on January 13, 2017, Plaintiffs were provided with access to 93,750 pages relating to BLA 761058, which included, *inter alia*, information concerning the process or processes used to manufacture the BLA Product ("the 2A Disclosure"). Defendants deny the remaining allegations of paragraph 53.

54. Admitted in part; denied in part. Defendants admit only that, on March 13, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A), counsel for Plaintiffs sent a letter to counsel for Defendants identifying the 72 patents of Plaintiffs' then-existing patents for which Plaintiffs alleged a claim of patent infringement could reasonably be asserted against the BLA Product ("the 3A List"), and that the letter included the quotation recited in paragraph 54 of the complaint. Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 54, and therefore deny the same.

55. Admitted in part; denied in part. Defendants admit only that, on April 18, 2017, June 6, 2017, and June 20, 2017, counsel for Plaintiffs provided supplemental lists to counsel for Defendants identifying certain issued patents.

56. Admitted in part; denied in part. Defendants admit only that, on May 12, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(B), counsel for Defendants provided counsel for Plaintiffs with 1,841 pages describing, in detail, bases for noninfringement and invalidity of the 72 patents identified on the 3A List ("the 3B Statement"); and that, on May 18, 2017, and July 6, 2017, pursuant to 42 U.S.C. § 262(*l*)(7), counsel for Defendants provided counsel for Plaintiffs with statements describing, in detail, bases for noninfringement and invalidity of the three patents identified in Plaintiffs' supplemental lists. Defendants deny the remaining allegations of paragraph 56.

57. Admitted in part; denied in part. Defendants admit only that, on July 11, 2017, Plaintiffs purported to respond to the 3B Statement ("the 3C Statement"), and that the 3C Statement provided by Plaintiffs purported to address the patents identified in the table included in paragraph 57 of the complaint (yet, in doing so, did not fulfill the requirements of 42 U.S.C. § 262(*l*)(3)(C)). Defendants deny the remaining allegations of paragraph 57.

58. Denied.

59. Admitted in part; denied in part. Defendants admit only that, after Plaintiffs provided the 3C Statement, Plaintiffs proposed litigating 71 patents; and that, pursuant to the procedures set forth in the BPCIA and the circumstances described in paragraph 7 above, counsel for Defendants notified counsel for Plaintiffs that each side could choose up to five patents (as opposed to the dozens of patents Plaintiffs proposed) to be litigated. Defendants deny the remaining allegations of paragraph 59.

60. Admitted.

61. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 61 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 61.

THE BLA PRODUCT

62. Admitted in part; denied in part. Defendants admit only that the BLA Product is being developed for distribution in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

63. Admitted in part; denied in part. Defendants admit only that BIPI submitted BLA 761058 to the FDA seeking approval of the BLA Product. Otherwise, denied.

64. Admitted in part; denied in part. Defendants admit only that the document cited in paragraph 64 refers to the acceptance of BLA 761058 by the FDA and is dated January 18, 2017. Otherwise, denied.

65. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 65 includes the quoted language. Otherwise, denied.

66. Admitted in part; denied in part. Defendants admit only that clinical trials have been conducted with regard to the use of the BLA Product for treatment of moderate to severe rheumatoid arthritis; that data from those clinical trials were submitted in connection with BLA 761058; and that clinical trials with regard to the use of the BLA Product for treatment of plaque psoriasis and Crohn's disease are ongoing. Otherwise, denied.

67. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 67 includes the quoted language. Otherwise, denied.

68. Admitted in part; denied in part. Defendants admit that, as of the date of the filing of Plaintiffs' complaint, the FDA had not yet approved the BLA Product. Otherwise, denied.

69. Admitted in part; denied in part. Defendants admit that a justiciable case or controversy exists between the parties, but deny that any act of infringement has occurred.

THE ADALIMUMAB PATENTS

70. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70, and therefore deny the same.

71. Admitted in part; denied in part. Defendants admit only that Plaintiffs are limited to asserting U.S. Patent Nos. 8,926,975 ("the '975 patent"), 9,018,361 ("the '361 patent"), 9,090,867 ("the '867 patent"), 9,096,666 ("the '666 patent"), 9,255,143 ("the '143 patent"), 9,266,949 ("the '949 patent"),9,272,041 ("the '041 patent"), and 9,546,212 ("the '212 patent") (collectively, the "Asserted Patents") in this lawsuit. Defendants deny the remaining allegations of paragraph 71.

72. Admitted.

73. Admitted in part; denied in part. Defendants admit only that, on January 6, 2015, the '975 patent, titled "Method of Treating Ankylosing Spondylitis," was issued by the United States Patent and Trademark Office ("USPTO"), and that Exhibit 8 appears to be a copy of the '975 patent. Otherwise, denied.

74. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '975 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 74, and therefore deny the same.

75. Admitted in part; denied in part. Defendants admit only that, on April 28, 2015, the '361 patent, titled "Isolation and Purification of Antibodies Using Protein A Affinity Chromatography," was issued by the USPTO, and that Exhibit 9 appears to be a copy of the '361 patent. Otherwise, denied.

76. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the ’361 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 76, and therefore deny the same.

77. Admitted in part; denied in part. Defendants admit only that, on July 28, 2015, the ’867 patent, titled “Fed-Batch Method of Making Anti-TNF-Alpha Antibody,” was issued by the USPTO, and that Exhibit 10 appears to be a copy of the ’867 patent. Otherwise, denied.

78. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the ’867 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 78, and therefore deny the same.

79. Admitted in part; denied in part. Defendants admit only that, on August 4, 2015, the ’666 patent, titled “Purified Antibody Composition,” was issued by the USPTO, and that Exhibit 11 appears to be a copy of the ’666 patent. Otherwise, denied.

80. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the ’666 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 80, and therefore deny the same.

81. Admitted in part; denied in part. Defendants admit only that, on February 9, 2016, the ’143 patent, titled “Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins,” was issued by the USPTO, and that Exhibit 12 appears to be a copy of the ’143 patent. Otherwise, denied.

82. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the ’143 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 82, and therefore deny the same.

83. Admitted in part; denied in part. Defendants admit only that, on February 23, 2016, the ’949 patent, titled “Low Acidic Species Compositions and Methods for Producing and Using the Same,” was issued by the USPTO, and that Exhibit 13 appears to be a copy of the ’949 patent. Otherwise, denied.

84. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the ’949 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 84, and therefore deny the same.

85. Admitted in part; denied in part. Defendants admit only that, on March 1, 2016, the ’041 patent, titled “Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders,” was issued by the USPTO, and that Exhibit 14 appears to be a copy of the ’041 patent. Otherwise, denied.

86. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the ’041 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 86, and therefore deny the same.

87. Admitted in part; denied in part. Defendants admit only that, on January 17, 2017, the ’212 patent, titled “Methods of Administering Anti-TNFα Antibodies,” was issued by the USPTO, and that Exhibit 15 appears to be a copy of the ’212 patent. Otherwise, denied.

88. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '212 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 88, and therefore deny the same.

89. Admitted.

90. Admitted in part; denied in part. Defendants admit that Plaintiffs purported to provide responses pursuant to 42 U.S.C. § 262(*l*)(3)(C) for certain claims of the Asserted Patents, but deny that those responses fulfilled the requirements of the BPCIA.

ANSWER TO COUNT I
(Alleged Infringement of the '975 Patent)

91. Defendants repeat and restate their responses to paragraphs 1-90 of the complaint as if fully set forth herein.

92. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

93. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

94. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

95. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

96. Denied.

97. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 97.

98. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 98.

99. Denied.

100. Denied.

101. Admitted.

102. Denied.

103. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT II
(Alleged Infringement of the '361 Patent)

104. Defendants repeat and restate their responses to paragraphs 1-103 of the complaint as if fully set forth herein.

105. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

106. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

107. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

108. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

109. Denied.

110. Denied.

111. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Admitted.

117. Denied.

118. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT III
(Alleged Infringement of the '867 Patent)

119. Defendants repeat and restate their responses to paragraphs 1-118 of the complaint as if fully set forth herein.

120. Defendants admit that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

121. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

122. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

123. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

124. Denied.

125. Denied.

126. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

131. Admitted.

132. Denied.

133. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT IV
(Alleged Infringement of the '666 Patent)

134. Defendants repeat and restate their responses to paragraphs 1-133 of the complaint as if fully set forth herein.

135. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

136. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

137. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

138. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

139. Denied.

140. Denied.

141. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Admitted.

147. Denied.

148. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT V
(Alleged Infringement of the '143 Patent)

149. Defendants repeat and restate their responses to paragraphs 1-148 of the complaint as if fully set forth herein.

150. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

151. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

152. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

153. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

154. Denied.

155. Denied.

156. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Admitted.

162. Denied.

163. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VI
(Alleged Infringement of the '949 Patent)

164. Defendants repeat and restate their responses to paragraphs 1-163 of the complaint as if fully set forth herein.

165. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

166. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

167. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

168. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

169. Denied.

170. Denied.

171. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

176. Admitted.

177. Denied.

178. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VII
(Alleged Infringement of the '041 Patent)

179. Defendants repeat and restate their responses to paragraphs 1-178 of the complaint as if fully set forth herein.

180. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

181. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

182. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

183. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

184. Denied.

185. Denied.

186. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

187. Denied.

188. Denied.

189. Denied.

190. Denied.

191. Admitted.

192. Denied.

193. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VIII
(Alleged Infringement of the '212 Patent)

194. Defendants repeat and restate their responses to paragraphs 1-193 of the complaint as if fully set forth herein.

195. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

196. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

197. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

198. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

199. Denied.

200. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 200.

201. Admitted in part; denied in part. Defendants deny the allegations of paragraph 201, except that Defendants admit that BLA 761058 includes information regarding the administration of the BLA Product.

202. Denied.

203. Denied.

204. Admitted.

205. Denied.

206. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT IX
(Declaratory Judgment for Alleged Infringement of the '975 Patent)

207. Defendants repeat and restate their responses to paragraphs 1-206 of the complaint as if fully set forth herein.

208. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

209. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

210. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

211. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

212. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

213. Denied.

214. Denied.

215. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 215.

216. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 216.

217. Denied.

218. Denied.

219. Admitted.

220. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

221. Denied.

ANSWER TO COUNT X
(Declaratory Judgment for Alleged Infringement of the '361 Patent)

222. Defendants repeat and restate their responses to paragraphs 1-221 of the complaint as if fully set forth herein.

223. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

224. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

225. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

226. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

227. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

228. Denied.

229. Denied.

230. Denied.

231. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

232. Denied.

233. Denied.

234. Denied.

235. Denied.

236. Admitted.

237. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

238. Denied.

ANSWER TO COUNT XI
(Declaratory Judgment for Alleged Infringement of the '867 Patent)

239. Defendants repeat and restate their responses to paragraphs 1-238 of the complaint as if fully set forth herein.

240. Admitted in part; denied in part. Defendants admit that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

241. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

242. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

243. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

244. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

245. Denied.

246. Denied.

247. Denied.

248. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Admitted.

254. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

255. Denied.

ANSWER TO COUNT XII
(Declaratory Judgment for Alleged Infringement of the '666 Patent)

256. Defendants repeat and restate their responses to paragraphs 1-255 of the complaint as if fully set forth herein.

257. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

258. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

259. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

260. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

261. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

262. Denied.

263. Denied.

264. Denied.

265. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

266. Denied.

267. Denied.

268. Denied.

269. Denied.

270. Admitted.

271. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

272. Denied.

ANSWER TO COUNT XIII
(Declaratory Judgment for Alleged Infringement of the '143 Patent)

273. Defendants repeat and restate their responses to paragraphs 1-272 of the complaint as if fully set forth herein.

274. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

275. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

276. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

277. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

278. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

279. Denied.

280. Denied.

281. Denied.

282. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

283. Denied.

284. Denied.

285. Denied.

286. Denied.

287. Admitted.

288. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

289. Denied.

ANSWER TO COUNT XIV
(Declaratory Judgment for Alleged Infringement of the '949 Patent)

290. Defendants repeat and restate their responses to paragraphs 1-289 of the complaint as if fully set forth herein.

291. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

292. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

293. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

294. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

295. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

296. Denied.

297. Denied.

298. Denied.

299. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

300. Denied.

301. Denied.

302. Denied.

303. Denied.

304. Admitted.

305. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

306. Denied.

ANSWER TO COUNT XV
(Declaratory Judgment for Alleged Infringement of the '041 Patent)

307. Defendants repeat and restate their responses to paragraphs 1-306 of the complaint as if fully set forth herein.

308. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise denied.

309. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

310. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

311. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

312. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

313. Denied.

314. Denied.

315. Denied.

316. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

317. Denied.

318. Denied.

319. Denied.

320. Denied.

321. Admitted.

322. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

323. Denied.

ANSWER TO COUNT XVI
(Declaratory Judgment for Alleged Infringement of the '212 Patent)

324. Defendants repeat and restate their responses to paragraphs 1-323 of the complaint as if fully set forth herein.

325. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

326. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

327. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

328. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

329. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

330. Denied.

331. Denied.

332. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 332.

333. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 333.

334. Denied.

335. Denied.

336. Admitted.

337. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

338. Denied.

PRAYER FOR RELIEF

The remainder of Plaintiffs' complaint recites a prayer for relief to which no response is required. To the extent any response is required, Defendants deny that Plaintiffs are entitled to any remedy or relief.

WHEREFORE Defendants respectfully request that the Court enter judgment in their favor, and against Plaintiffs, along with attorney fees, costs of suit, and such other and further relief as the Court deems appropriate.

DEFENSES

Without prejudice to the denials set forth in their Answer, and without admitting any allegation of the complaint not expressly admitted herein, Defendants assert the following separate defenses to the complaint without assuming the burden of proof on any such defense

that would otherwise rest with Plaintiffs. Defendants expressly reserve their rights to assert additional defenses that discovery may reveal.

FIRST DEFENSE
(Failure to State a Claim)

1. Plaintiffs' complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE
(Noninfringement of the Asserted Patents)

2. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '975 patent.

3. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '361 patent.

4. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '867 patent.

5. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '666 patent.

6. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '143 patent.

7. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '949 patent.

8. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '041 patent.

9. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '212 patent.

THIRD DEFENSE
(Invalidity of the Asserted Patents)

10. The claims of the ’975 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

11. The claims of the ’361 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

12. The claims of the ’867 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

13. The claims of the ’666 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

14. The claims of the ’143 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

15. The claims of the ’949 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

16. The claims of the ’041 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

17. The claims of the ’212 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

FOURTH DEFENSE
(§ 271(e) Safe Harbor)

18. To the extent Plaintiffs claim that the manufacture and clinical use of the BLA Product is an act of infringement, Defendants are exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e).

FIFTH DEFENSE
(Prohibition of Costs)

19. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

SIXTH DEFENSE
(No Exceptional Case)

20. Defendants’ actions related to this case do not give rise to an exceptional case finding under 35 U.S.C. § 285.

SEVENTH DEFENSE
(No Equitable Relief)

21. Plaintiffs are not entitled to preliminary or permanent equitable relief.

EIGHTH DEFENSE
(BPCIA Noncompliance)

22. Plaintiffs cannot maintain a cause of action for any of the asserted patents because they have not complied with the BPCIA.

NINTH DEFENSE
(Unclean Hands)

23. Plaintiffs cannot obtain relief, including injunctive relief, because of unclean hands.

RESERVATION OF DEFENSES

24. Defendants reserve the right to assert any additional defenses or counterclaims, at law or equity, which may exist.

WHEREFORE Defendants respectfully request that the Court enter judgment in their favor, and against Plaintiffs, along with attorney fees, costs of suit, and such other and further relief as the Court deems appropriate.

COUNTERCLAIMS

Defendants hereby counterclaim against Plaintiffs as follows:

PARTIES

1. BII is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

2. BIPI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. BIFI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6701 Kaiser Drive, Fremont, California 94555.

4. On information and belief, AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. On information and belief, AbbVie Biotechnology Ltd is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

JURISDICTION AND VENUE

6. Defendants' counterclaims for declaratory judgments of invalidity and noninfringement arise under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq*. This Court has subject matter jurisdiction to hear Defendants' counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Plaintiffs because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing the above-captioned action (C.A. No. 17-cv-01065-MSG) against Defendants in the District of Delaware.

8. Venue with respect to the counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400. Plaintiffs allege that venue is proper in this District in their complaint.

9. An actual and justiciable controversy has arisen and now exists between the parties because, among other reasons, Plaintiffs have filed the above-captioned action against Defendants in the District of Delaware alleging infringement of the Asserted Patents. As explained in detail below, the present lawsuit stems from Plaintiffs' attempts to improperly extend their monopoly on adalimumab, the active ingredient of the drug Humira®.

BACKGROUND

The BLA Product

10. Defendants are part of one of the world's leading pharmaceutical groups. With a history dating back to 1885, there are now 143 global Boehringer affiliates employing more than 45,600 people. Boehringer companies have spent decades developing innovative therapies to improve the lives of patients. In 2016 alone, Boehringer companies invested more than $3.3 billion on the research and development of new medicines, including treatments for immunology and respiratory disorders, cardiovascular and metabolic diseases, cancer, and diseases of the central nervous system.

11. Boehringer companies have been pioneers in the field of biologic medicines, with over 35 years of experience and more than 25 drugs manufactured. Biologics produced by Boehringer companies include monoclonal antibodies in oncology and immunology, interferons, and other targeted medicines. AbbVie Inc. itself recently partnered with a Boehringer company to develop two therapeutic antibody candidates invented by Boehringer, BI 655066 and BI 655064, which included an initial payment of $595 million from AbbVie Inc. (*See* Ex. A, Press Release, AbbVie, AbbVie and Boehringer Ingelheim Announce Global Collaboration on Promising Immunology Compounds (Mar. 7, 2016) at *1, 4.)

12. The BLA Product is an injectable formulation containing adalimumab as the active ingredient. Adalimumab and a biologic drug product containing adalimumab were disclosed and claimed in a patent application filed in 1996 that issued as the now-expired ’382 patent. The ’382 patent conferred a statutory monopoly and attendant exclusivity in the United States to Plaintiffs for more than 16 years (from its issuance on July 18, 2000, to its expiration on December 31, 2016), excluding others from adalimumab, formulations containing adalimumab, and methods of making and using adalimumab. Plaintiffs further relied on clinical trials performed with adalimumab to gain an extension of the ’382 patent term under 35 U.S.C. § 156.

Plaintiffs Purchase Adalimumab and Create a Patent Thicket

13. The antibody adalimumab was originally developed through a collaboration between BASF AG and Cambridge Antibody Technology. Adalimumab was disclosed in U.S. Application No. 08/599,226, filed on February 9, 1996, which later issued as the ’382 patent. BASF AG was the original assignee for the ’382 patent.

14. On information and belief, on December 14, 2000, Plaintiffs’ predecessor, Abbott Laboratories (“Abbott”), entered into an agreement to purchase BASF AG’s pharmaceutical

business, thus acquiring rights to the adalimumab antibody. On information and belief, the purchase was completed on March 2, 2001.

15. The adalimumab antibody was approved by the FDA for use in treating humans on December 31, 2002.

16. During the nearly 15 years since adalimumab's approval by the FDA, Abbott (and subsequently Plaintiffs) have marketed adalimumab under the trade name Humira®. At times during the period of exclusivity of the '382 patent, Humira® has cost nearly $50,000 per year. (Ex. B, Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. TIMES, (July 16, 2016), https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html at *1 ("Pollack 2016").) In 2016, global sales of Humira® totaled $16.078 billion. (Ex. C, *AbbVie Reports Full-Year and Fourth-Quarter 2016 Financial Results*, ABBVIE PRESSROOM (Jan. 17, 2017), https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2016-financial-results.htm at *1.)

17. During pre-suit BPCIA exchanges related to the BLA product, Plaintiffs identified a total of 75 patents pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7).

18. As of the time of FDA approval of adalimumab in 2002, the only patent of the 75 patents identified by Plaintiffs in pre-suit exchanges pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7) that had issued was the '382 patent. Plaintiffs have acknowledged that the '382 patent would not be infringed by the BLA Product.

19. As of the year 2011, nine years later, the only patent of the 75 patents identified by Plaintiffs in pre-suit exchanges pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7) that had issued was the '382 patent.

20. As of 2001, when Abbott acquired rights to the adalimumab antibody, it was aware of the expiration of the '382 patent in December 2016, which had created exclusivity in, *inter alia*, adalimumab, formulations containing adalimumab, and methods of making and using adalimumab.

21. On information and belief, Plaintiffs engaged in a pattern of pursuing numerous overlapping and non-inventive patents for the purpose of developing a "patent thicket," using the patenting process itself as a means to seek to delay competition against its expensive and lucrative adalimumab product. That strategy has generated, according to paragraph 18 of Plaintiffs' complaint, more than 100 patents.

22. All 74 patents listed in paragraphs 57-58 of Plaintiffs' complaint, which Plaintiffs identified as the then-existing patents for which a claim of patent infringement could reasonably be asserted with respect to the BLA Product, were issued between 2012 and 2017.

23. All 74 patents identified in paragraphs 57-58 of the complaint stem from less than half as many patent families. Many of the patents identified by Plaintiffs share common specifications and have overlapping and nearly identical claims. (*See, e.g.*, U.S. Patent Nos. 8,802,100, 8,802,101, 8,916,157, 8,916,158, 9,114,166, 9,220,781, and 9,302,011, and the '041 patent.) Many of Plaintiffs' patents from different families also have substantially similar disclosures and claims, despite claiming priority to different applications. (*See, e.g.*, U.S. Patent Nos. 9,346,879 and 9,315,574.)

24. On information and belief, Plaintiffs have made public statements citing the existence of the patent thicket as a reason for delaying competition for adalimumab. (*See, e.g.*, Ex. B, Pollack 2016 at *3 (quoting AbbVie Inc. CEO Richard A Gonzalez, "Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent

estate, which AbbVie intends to enforce vigorously."); Ex. D, Excerpt from Abbott Laboratories, Annual Report at 7 (Form 10-K) (Feb. 25, 2004) (describing the purpose of patents directed to formulations, uses, or manufacturing processes as potentially extending Abbott's drug product exclusivity).)

Plaintiffs' Asserted Patents Do Not Represent Innovation

25. As will be shown in this litigation, Plaintiffs' patents do not represent innovation, but rather are attempts to claim methods of treatment, methods of production, and formulations derived from the prior art for the purpose of creating a patent thicket or estate that competitors must, as AbbVie has publicly stated, "contend with" to sell the active ingredient previously disclosed and claimed in the now-expired '382 patent.

26. Humira®'s success is not due to the alleged inventions of the patents Plaintiffs now assert against Defendants, but rather is because of the properties of its active ingredient, adalimumab. Adalimumab was the first fully human monoclonal antibody approved by the FDA, and as such represented a true scientific achievement. The formulations, production processes, and dosing regimens claimed in Plaintiffs' patent estate are not.

27. During *inter partes* review ("IPR") proceedings against U.S. Patent No. 8,889,135 ("the '135 patent"), which is directed to certain methods of treating rheumatoid arthritis using adalimumab, AbbVie Biotechnology Ltd's commercial success expert acknowledged that adalimumab's status as the first fully human monoclonal antibody was a significant reason for Humira®'s commercial success. (*E.g.*, Ex. E, Excerpt from 1/4/17 Deposition Transcript of Jerry Hausman, Ph.D. at 49:23-50:4, IPR2016-00408.)

28. In its final decisions in connection with IPR2016-00408 and IPR2016-00409, the Patent Trial and Appeal Board ("PTAB") concluded that, *inter alia*, AbbVie Biotechnology Ltd had not shown that Humira®'s commercial success was due to the claimed method of treatment,

as opposed to the already known and patented adalimumab antibody. (*See* Ex. F, IPR2016-00408 at 41 (P.T.A.B. July 6, 2017); Ex. G, IPR2016-00409 at 43 (P.T.A.B. July 6, 2017).) The PTAB further stated, "[I]t appears from the evidence that the driving force behind the satisfaction of a long-felt need and success where others had failed was the introduction of the first fully human anti-TNFα antibody, not the claimed dosing regimen." (Ex. F, IPR2016-00408 at 42; Ex. G, IPR2016-00409 at 44.)

29. The claims of the '135 patent were found unpatentable in decisions by the PTAB on May 16, 2017, and July 6, 2017.

30. The claims of U.S. Patent Nos. 9,017,680 ("the '680 patent") and 9,073,987 ("the '987 patent"), which are also directed to methods of treating rheumatoid arthritis using adalimumab, were found unpatentable by the PTAB on June 9, 2017.

31. Plaintiffs allege in their complaint that the '135, '680, and '987 patents could reasonably be asserted with respect to the BLA Product, even though these patents were found unpatentable by the PTAB.

32. On March 3, 2017, the United Kingdom High Court found methods of treating rheumatoid arthritis, psoriatic arthritis, and psoriasis claimed in European Patents EP 1,406,656, EP 1,944,322, and EP 2,940,044 to be obvious and/or anticipated in light of the prior art. (*See* Ex. H, *Fujifilm Kyowa Kirin Biologics Co. v. AbbVie Biotech. Ltd* ("the *Fujifilm* Action") [2017] EWHC (Pat) 395 [3]-[4], [415] (Eng.) (granting declarations that petitioner's biosimilar products to be administered using claimed methods were obvious and/or anticipated as of priority dates for subject patents).)

33. The United Kingdom High Court reached a final ruling on invalidity in the *Fujifilm* Action despite the fact that AbbVie Biotechnology Ltd revoked or de-designated its

patents with respect to the United Kingdom during the proceedings, noting that AbbVie Biotechnology Ltd's gamesmanship warranted a decision on the merits. The United Kingdom High Court stated:

> The Claimants allege that the object and cumulative consequence of AbbVie's conduct is intended to delay the entry of competing biosimilars, and AbbVie has sought to achieve this by prolonging commercial uncertainty by a series of acts of abandonment of protection, whilst re-filing divisionals for essentially the same subject matter. This puts into issue AbbVie's intentions, which I do not accept are irrelevant, on the basis of the pleaded issues. However, even if I were to consider only the objective effect of AbbVie's conduct, my conclusions would be no different. I consider that the intention and the objective effect is to shield its patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten infringement proceedings against biosimilars, wherever they may be launched.

(*Id*. at [388].)

34. Plaintiffs' efforts to create a patent thicket or estate in the United States are part of a global effort to improperly delay competition with respect to adalimumab.

Defendants' Compliance with the BPCIA and
Plaintiffs' Failure to Provide Evidence of Infringement

35. The BPCIA created an abbreviated approval pathway for biosimilar therapies. The statute balances incentives for reference product sponsors to develop new active ingredients with the critical importance of promoting competition and ensuring patients' access to biologic medicines at efficient prices within the United States.

36. To incentivize the development of new biologics, the BPCIA permits 12 years of exclusivity for a reference product before a biosimilar may be licensed. *See* 42 U.S.C. § 262(k)(7)(A). The BPCIA also sets forth specific steps regarding pre-suit disclosures and exchanges for patent litigation in connection with a biosimilar application.

37. BIPI submitted BLA 761058 to the FDA on October 27, 2016. On January 9, 2017, counsel for Defendants notified counsel for Plaintiffs that BLA 761058 had been accepted for review.

38. Pursuant to 42 U.S.C. § 262(*l*)(2)(A), on January 13, 2017, counsel for Defendants provided Plaintiffs with access to 93,750 pages relating to BLA 761058, which included, *inter alia*, information concerning "the process or processes used to manufacture" the BLA Product.

39. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs made no assertion that Defendants did not comply with the BPCIA.

40. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs did not notify Defendants that any manufacturing information necessary for Plaintiffs' assessment was missing from the 2A Disclosure.

41. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs did not request permission for any outside experts to view the 2A Disclosure or express any issue with any alleged limitation on access for outside experts.

42. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on March 13, 2017, counsel for Plaintiffs sent a letter to counsel for Defendants identifying the 72 patents of Plaintiffs' then-existing

patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product.

43. The 3A List included the ’382 patent, even though that patent had expired on December 31, 2016.

44. Plaintiffs’ inclusion of the ’382 patent on the 3A List was consistent with an attempt to improperly extend a statutory monopoly based on that patent and to impede competition.

45. The 3A List also included the ’135, ’680, and ’987 patents. Paragraph 57 of Plaintiffs’ complaint continues to allege these patents could reasonably be asserted with respect to the BLA Product, even though these patents were found unpatentable by the PTAB before the filing of Plaintiffs’ complaint.

46. On April 18, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing the 3A List with U.S. Patent No. 9,624,295 (“the ’295 patent”) pursuant to 42 U.S.C. § 262(*l*)(7).

47. Pursuant to 42 U.S.C. § 262(*l*)(3)(B), on May 12, 2017, counsel for Defendants provided Plaintiffs with 1,841 pages describing in detail bases for noninfringement and invalidity of all 72 patents identified on the 3A List.

48. Pursuant to 42 U.S.C. § 262(*l*)(7), on May 18, 2017, counsel for Defendants provided Plaintiffs with a statement describing in detail bases for noninfringement and invalidity of the ’295 patent.

49. On June 6, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing their 3A List with U.S. Patent No. 9,669,093 (“the ’093 patent”) pursuant to 42 U.S.C. § 262(*l*)(7).

50. On June 20, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing their 3A List with U.S. Patent No. 9,683,033 ("the '033 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

51. On July 6, 2017, counsel for Defendants provided Plaintiffs with statements describing in detail bases for noninfringement and invalidity of the '093 and '033 patents pursuant to 42 U.S.C. § 262(*l*)(7).

52. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs made no assertion that Defendants did not comply with the BPCIA.

53. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs did not notify Defendants that any manufacturing information necessary for Plaintiffs' assessment was missing from the 2A Disclosure.

54. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs did not request permission for any outside experts to view the 2A Disclosure or express any issue with any alleged limitation on access for outside experts.

55. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), on July 11, 2017, counsel for Plaintiffs provided responses alleging infringement and validity for 71 of the 72 patents addressed in the 3B Statement. In the 3C Statement, Plaintiffs acknowledged that the BLA Product would not infringe the '382 patent.

56. In the 3C Statement, Plaintiffs did not withdraw infringement allegations for the ’135, ’680, and ’987 patents, despite the fact that these patents had previously been found unpatentable by the PTAB.

57. Among other deficiencies, the 3C Statement failed to provide evidence for many claims that Plaintiffs alleged, and continue to allege, would be infringed by the BLA Product. Plaintiffs omitted claims entirely from claim charts they provided purporting to set forth bases for infringement, including, for example, claims 3, 8-15, 20, and 24-27 of the ’041 patent. For many other claims (*e.g.*, all claims of the ’666 patent), Plaintiffs provided a boilerplate statement alleging that they possessed insufficient evidence relating to the BLA Product, and also (incorrectly) contended that Plaintiffs were “not permitted under their confidentiality agreements with BI to consult with independent experts regarding BI confidential information.”

58. In their 3C Statement, Plaintiffs, for the first time, alleged that information allegedly needed for their infringement analyses was not included in the 2A Disclosure.

59. In their 3C Statement, Plaintiffs, for the first time, alleged that they were not permitted to consult with outside experts based on the parties’ confidentiality undertaking.

60. The language of the parties’ confidentiality undertaking, which was agreed to on January 15, 2017, after careful negotiation, expressly contemplates outside experts reviewing the 2A Disclosure with written permission. (*See* Ex. I, E-mail from Arianna Evers to Hassen A. Sayeed (Jan. 15, 2017).) AbbVie attorneys signed the undertaking, which states in paragraph 4, “For the avoidance of doubt, I understand and agree that I may not disclose any confidential information in Boehringer’s 2A Disclosure to . . . any outside scientific consultants . . . without the prior written consent of Boehringer.” This language tracks the language of the BPCIA itself. *See* 42 U.S.C. § 262(*l*)(1)(C) (“No person that receives confidential information pursuant to

subparagraph (B) shall disclose any confidential information to any other person or entity, including . . . scientific consultants retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.").

61. Plaintiffs did not raise any issue with the confidentiality undertaking's expert provisions during the parties' negotiations regarding that document from January 12, 2017, to January 15, 2017.

62. Plaintiffs did not identify any outside experts for which confidential access was sought pursuant to the undertaking.

63. Between January 13, 2017, and July 11, 2017, Plaintiffs sought, and were granted, permission for 43 outside attorneys and law firm technical advisors (including at least 14 attorneys with Ph.D. degrees) to view the 2A Disclosure. On May 25, 2017, and June 27, 2017, Plaintiffs sought permission for in-house attorneys to view confidential information in excess of the number permitted by statute under 42 U.S.C. § 262(*l*)(1)(B)(ii)(II). Although Plaintiffs sought permission for outside and in-house counsel to review confidential information, Plaintiffs did not seek permission for any outside scientific consultants, or raise this as an issue before submitting the 3C Statement.

64. On July 13, 2017, in a teleconference with Defendants' counsel, Plaintiffs' counsel proposed litigating 71 of the patents identified on the 3A List (all except the '382 patent) in a single litigation. Plaintiffs' proposal included the '135, '680, and '987 patents, whose claims have been found unpatentable by the PTAB.

65. On July 21, 2017, in response to Plaintiffs' deficient 3C Statement and Plaintiffs' proposal to litigate 71 patents — many of which, as explained in paragraph 22 of Defendants' counterclaims above, have common or similar specifications and overlapping, nearly identical

claims — in a single litigation, counsel for Defendants sent Plaintiffs a letter seeking removal of at least 16 patents for which Plaintiffs expressly admitted in their 3C Statement that they lacked sufficient evidence to allege infringement ("the July 21, 2017 Letter"). Plaintiffs declined to remove any of the 16 patents.

66. On July 26, 2017, within the time period expressly contemplated by the BPCIA under 42 U.S.C. § 262(*l*)(4)(b) and pursuant to 42 U.S.C. § 262(*l*)(5)(A), counsel for Defendants notified Plaintiffs that each side could select up to five patents to litigate in the present action.

67. On July 31, 2017, pursuant to 42 U.S.C. § 262(*l*)(5)(B), the lists of patents to be litigated in the present action were exchanged. Counsel for Plaintiffs identified the '975 patent, the '361 patent, the '949 patent, the '041 patent, and the '212 patent. Counsel for Defendants identified the '867 patent, the '666 patent, and the '143 patent, as well as the '975 patent and the '041 patent.

68. On August 2, 2017, Plaintiffs filed the present action alleging infringement of the eight non-overlapping patents.

69. Because, *inter alia*, Plaintiffs are aware that they expressed no factual basis for asserting infringement in the 3C Statement (and thus did not comply with the BPCIA) for at least the 16 patents identified in the July 21, 2017 Letter, Plaintiffs' complaint miscites 35 U.S.C. § 295 for the erroneous premise that it is Defendants' burden to prove noninfringement. 35 U.S.C. § 295, *inter alia*, does not address the standards for pre-suit investigation and is not applicable here.

70. As of July 11, 2017, when the 3C Statement was served, Plaintiffs acknowledged that they lacked a good-faith basis to assert infringement of at least the '666 patent and the '143 patent, among many others.

71. In their complaint, Plaintiffs allege that the BLA Product would infringe patents that Plaintiffs admitted they lack a reasonable basis to assert in the 3C Statement.

72. In their complaint, Plaintiffs allege that the BLA Product would infringe patents that have been found unpatentable by the PTAB.

73. Plaintiffs' continued assertion of patents that Plaintiffs have no basis to assert, including patents found unpatentable by the PTAB, is part of a pattern of anticompetitive behavior designed to delay Defendants' entrance into the market and improperly extend Plaintiffs' monopoly over adalimumab.

74. Defendants reserve the right to pursue in this action any and all defenses and remedies based upon Plaintiffs' improper behavior.

COUNT I
(Declaration of Noninfringement and Invalidity of the '975 Patent)

75. The averments of paragraphs 1-74 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

76. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the '975 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '975 patent in the United States.

77. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '975 patent.

78. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '975 patent under 35 U.S.C. § 271.

79. The claims of the ’975 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

80. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Noninfringement and Invalidity of the ’361 Patent)

81. The averments of paragraphs 1-80 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

82. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the ’361 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’361 patent in the United States.

83. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’361 patent.

84. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’361 patent under 35 U.S.C. § 271.

85. The claims of the ’361 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

86. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Noninfringement and Invalidity of the ’867 Patent)

87. The averments of paragraphs 1-86 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

88. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the ’867 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’867 patent in the United States.

89. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’867 patent.

90. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’867 patent under 35 U.S.C. § 271.

91. The claims of the ’867 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

92. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Noninfringement and Invalidity of the ’666 Patent)

93. The averments of paragraphs 1-92 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

94. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the ’666 patent. Plaintiffs have alleged

that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’666 patent in the United States.

95. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’666 patent.

96. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’666 patent under 35 U.S.C. § 271.

97. The claims of the ’666 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

98. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT V
(Declaration of Noninfringement and Invalidity of the ’143 Patent)

99. The averments of paragraphs 1-98 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

100. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the ’143 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’143 patent in the United States.

101. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’143 patent.

102. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’143 patent under 35 U.S.C. § 271.

103. The claims of the ’143 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

104. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Noninfringement and Invalidity of the ’949 Patent)

105. The averments of paragraphs 1-104 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

106. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the ’949 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’949 patent in the United States.

107. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’949 patent.

108. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’949 patent under 35 U.S.C. § 271.

109. The claims of the ’949 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

110. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VII
(Declaration of Noninfringement and Invalidity of the ’041 Patent)

111. The averments of paragraphs 1-110 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

112. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the ’041 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’041 patent in the United States.

113. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’041 patent.

114. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’041 patent under 35 U.S.C. § 271.

115. The claims of the ’041 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

116. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VIII
(Declaration of Noninfringement and Invalidity of the ’212 Patent)

117. The averments of paragraphs 1-116 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

118. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the ’212 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’212 patent in the United States.

119. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’212 patent.

120. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’212 patent under 35 U.S.C. § 271.

121. The claims of the ’212 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, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

122. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court enter:

A. An entry of judgment on Plaintiffs’ complaint in favor of Defendants, and against Plaintiffs, with Plaintiffs not being awarded any relief thereon;

B. A declaratory judgment that Defendants have not infringed and will not infringe any valid and enforceable claim of the Asserted Patents under 35 U.S.C. § 271;

C. A declaratory judgment that the Asserted Patents are invalid;

D. An Order enjoining and restraining Plaintiffs and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from pursuing further charges of infringement or acts of enforcement based on the Asserted Patents against Defendants or their actual and prospective business partners, customers, suppliers, clinical investigators, and anyone in privity with Defendants;

E. A judgment that this case is exceptional and that Defendants are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285;

F. An award of costs, expenses, and attorney fees pursuant to 28 U.S.C. § 1927;

G. An award of taxable costs;

H. An award of interest;

I. An Order for such other and further relief as the Court deems just and proper.

Dated: September 11, 2017

Respectfully submitted,

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