IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| GENENTECH, INC. and CITY OF HOPE,<br><br>Plaintiffs and Counterclaim Defendants,<br><br>v.<br><br>PFIZER INC.,<br><br>Defendant and Counterclaim Plaintiff. | ) | C.A. No. 1:19-cv-00638-CFC |
| PFIZER INC.,<br><br>Counterclaim Plaintiff,<br><br>v.<br><br>HOFFMAN-LA ROCHE, INC.,<br><br>Counterclaim Defendant. | ) | |

**DEFENDANT PFIZER INC.'S ANSWER,**
**AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant and Counterclaim-Plaintiff Pfizer Inc. ("Pfizer"), by and through its attorneys, hereby submits this Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech" or "Plaintiffs") on April 5, 2019 (the "Complaint"). Counterclaims related to the patents assigned to Hoffman-La Roche, Inc. are also asserted against Hoffman-La Roche, Inc. ("Roche").

## ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs (each a "Paragraph") in the Complaint. Pfizer denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations,

implications, or speculations that arguably follow from the admitted facts. Moreover, to the extent that any of Plaintiffs' allegations are vague and/or ambiguous, Pfizer denies said allegations. Pfizer denies that Genentech is entitled to the relief requested or any other relief. Pfizer responds to the Complaint as follows:

**NATURE OF THE CASE**

1. Pfizer admits that Avastin® contains a genetically engineered antibody, bevacizumab, that inhibits the proliferation of blood vessels necessary for cancerous tumors to grow and that the Food and Drug Administration ("FDA") first approved Avastin® in 2004. Pfizer also admits that Avastin® is approved for certain specific indications. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 1 and, therefore, denies the same.

2. Pfizer admits that the Biologics Price Competition and Innovation Act ("BPCIA") was enacted in 2010 as part of the Affordable Care Act and that it provides for abbreviated regulatory approval for biosimilars. Pfizer admits that the BPCIA allows applicants to rely on certain clinical testing conducted by the innovator company. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 2 and, therefore, denies the same.

3. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 3 and, therefore, denies the same.

4. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 4 and, therefore, denies the same.

5. Pfizer admits that 42 U.S.C. § 242 (*l*)(2) states that "[n]ot later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for

review, the subsection (k) applicant (A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application . . . ." Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 5 and, therefore, denies the same.

6. Pfizer admits that 42 U.S.C. § 242 (*l*)(3)(A) provides that "[n]ot later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and (ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant." Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 6 and, therefore, denies the same.

7. Pfizer admits that on September 7, 2018, Genentech sent a letter purporting to identify "a list of exemplary information concerning processes used to manufacture a biological product" and requesting that Pfizer provide the information. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 7 and, therefore, denies the same.

8. Pfizer admits that on September 14, 2018, Pfizer produced its BLA to Genentech. Pfizer's BLA contains over 565,000 pages of information on Pfizer's Product and the processes to manufacture it. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. To the extent that portions of Pfizer's aBLA were not produced, those portions are not relevant or necessary for Genentech to understand the process or processes used to manufacture Pfizer's product. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 8 and, therefore, denies the same.

9. Pfizer admits that on September 17, 2018, Genentech sent a letter identifying purported deficiencies in Pfizer's September 12, 2018 production and offering to discuss an extension to the deadline pursuant to 42 U.S.C. § 242 (*l*)(2). Pfizer's September 14, 2018 production complied with the provisions of 42 U.S.C. § 242 (*l*)(2). Pfizer denies the remaining allegations of Paragraph 9.

10. Pfizer admits that on September 19, 2018, Pfizer sent a letter to Genentech stating that its September 14, 2018 production complied with the provisions of 42 U.S.C. § 242 (*l*)(2) and disagreeing with Genentech that Pfizer's aBLA must be produced as "PDF files capable of hyperlinking to each other." Pfizer denies the remaining allegations of Paragraph 10.

11. Pfizer admits that the parties exchanged correspondence over purported deficiencies in Pfizer's September 14, 2018 production and that Pfizer did not supplement its September 14, 2018 production prior to the deadline for Genentech to serve its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer's September 14, 2018 production complied with the provisions of 42 U.S.C. § 242 (*l*)(2). Pfizer denies the remaining allegations of Paragraph 11.

12. Pfizer admits that on November 13, 2018, Genentech purported to serve a list of 31 patents pursuant to 42 U.S.C. § 262(l)(3)(A). Pfizer denies that Genentech did "not hav[e] all the information to which it was entitled under the BPCIA to evaluate whether Pfizer's manufacture and sale of its proposed biosimilar Avastin® product ('Pfizer's aBLA product', 'its aBLA Product') would infringe Genentech's patents." Pfizer's September 14, 2018 production complied with the provisions of 42 U.S.C. § 242 (*l*)(2).

13. Pfizer admits that on December 21, 2018, it served disclosures pursuant to 42 U.S.C. § 262(*l*)(3)(B). To the extent that Genentech is alleging that Pfizer's disclosures were not in compliance with 42 U.S.C. § 262(*l*)(3)(B), Pfizer denies such an allegation. Pfizer's disclosures were in compliance with 42 U.S.C. § 262(*l*)(3)(B). Pfizer admits that on January 18, 2019, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its BLA product as early as July 17, 2019 (180 days from the date of the notice) pursuant to 42 U.S.C. § 262(*l*)(8)(A).

14. Pfizer admits that on February 19, 2019 Genentech purported to provide Pfizer with its statement asserting that the manufacture, use, sale, offer for sale, or importation of Pfizer's aBLA product would infringe 23 patents (its "(3)(C) Statement") pursuant to 42 U.S.C. § 262(*l*)(3)(C), which purported to include the factual and legal basis of its opinion that 17 patents will be infringed by the commercial marketing of Pfizer's aBLA product, as well as a response to Pfizer's December 21, 2018 statement concerning validity and enforceability for those patents. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 14 and, therefore, denies the same.

15. Admitted.

16. Pfizer admits that 42 U.S.C. § 262(*l*)(6)(A) provides that "if the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent." Pfizer admits that once the subsection (k) applicant has provided notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8), the reference product sponsor is permitted to file an action for declaratory judgment of patent infringement. Pfizer admits that Genentech's complaint purports to bring this action for infringement, declaratory judgment, an injunction, and any additional appropriate relief and to seek an order declaring that Pfizer's actions are contrary to the BPCIA and that the manufacture, use, offer for sale, sale, and/or importation of Pfizer's proposed biologic product infringes Plaintiffs' intellectual property rights, and an order enjoining Pfizer from infringing the Asserted Patents (as listed below), including by offering to sell or selling its aBLA product until after the expiration of the last-to-expire of the Asserted Patents. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 16 and, therefore, denies the same.

**PARTIES**

17. On information and belief, admitted.

18. On information and belief, Pfizer admits that Genentech was founded in 1976. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 18 and, therefore, denies the same.

19. On information and belief, admitted.

20. On information and belief, Pfizer admits that City of Hope was founded in 1913. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20 and, therefore, denies the same.

21. Admitted.

22. Pfizer admits that it is seeking licensure in the United States pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of Pfizer's aBLA Product, which is a biological product. Pfizer admits that Pfizer's aBLA Product will be distributed in the United States, including the State of Delaware, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer otherwise denies the allegations of Paragraph 22.

**JURISDICTION AND VENUE**

23. Pfizer admits that the Complaint purports to bring an action under the BPCIA, 42 U.S.C. § 262(*l*) and the Patent Laws of the United States, Title 35, United States Code. Pfizer denies that Genentech is entitled to any relief in this action. The remaining allegations of Paragraph 23 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 23.

24. Pfizer does not contest venue for purposes of this action only. Pfizer admits that Pfizer is incorporated in Delaware. The remaining allegations of Paragraph 24 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 24.

25. Pfizer admits that it is a corporation incorporated in Delaware. Pfizer admits that it has filed aBLA No. 761099 with the FDA seeking approval to market Pfizer's aBLA Product described therein. Pfizer does not contest personal jurisdiction for purposes of this action only.

The remaining allegations of Paragraph 25 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 25.

**FACTUAL BASIS FOR RELIEF**

26. Admitted.

27. Pfizer admits that the BPCIA allows applicants to rely on certain clinical testing conducted by the innovator company. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 27 and, therefore, denies the same.

28. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 28 and, therefore, denies the same.

**THE ASSERTED PATENTS**

29. Pfizer admits that Genentech served on November 13, 2018 a list of 31 patents that Genentech believed could reasonably be asserted against the manufacture, use, sale, offer for sale, or import into the United States of Pfizer's aBLA Product. See 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 29.

30. Admitted.

31. Admitted.

32. Pfizer admits that the Complaint purports to assert infringement of the patents listed in Paragraph 32. Pfizer denies the remaining allegations of Paragraph 32.

33. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 33 and, therefore, denies the same.

**COUNT ONE**

**(Infringement of the '297 Patent)**

34. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

35. Pfizer admits that United States Patent No. 6,054,297 ("the '297 patent") was issued by the United States Patent and Trademark Office ("PTO") on April 25, 2000. Pfizer admits that what Genentech purports to be a copy of the '297 patent was attached to the Complaint as Exhibit A. Pfizer denies the remaining allegations of Paragraph 35.

36. Pfizer admits that the '297 patent expired on February 26, 2018. Pfizer denies the remaining allegations of Paragraph 36.

37. Denied.

38. Denied.

39. Pfizer admits that if its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer admits that it manufactured some aBLA product before the expiry of the '297 patent that was solely for uses reasonably related to the development and submission of information to the FDA in connection with Pfizer's BLA. Pfizer's activities prior to the expiration of the '297 patent are protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1). Pfizer denies the remaining allegations of Paragraph 39.

40. Pfizer admits that it has knowledge of and is aware of the '297 patent. Pfizer admits that U.S. Patent No. 7,449,616 to which Pfizer is listed as an assignee cites to a U.S. Patent No. 6,054,297. Pfizer admits that Genentech disclosed the '297 patent on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer's proposed biosimilar Herceptin® product. Pfizer denies the remaining allegations of Paragraph 40.

41. Denied.

42. Denied.

43. Denied.

**COUNT TWO**

**(Infringement of the '428 Patent)**

44. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

45. Pfizer admits that United States Patent No. 6,121,428 ("the '428 patent") was issued by the United States Patent and Trademark Office ("PTO") on September 19, 2000. Pfizer admits that what Genentech purports to be a copy of the '428 patent was attached to the Complaint as Exhibit B. Pfizer denies the remaining allegations of Paragraph 45.

46. Pfizer admits that the '428 patent expired on June 12, 2018. Pfizer denies the remaining allegations of Paragraph 46.

47. Denied.

48. Denied.

49. Pfizer admits that if its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer admits that it manufactured some aBLA product before the expiry of the '428 patent that was solely for uses reasonably related to the development and submission of information to the FDA in connection with Pfizer's BLA. Pfizer's activities prior to the expiration of the '428 patent are protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1). Pfizer denies the remaining allegations of Paragraph 49.

50. Pfizer admits that it has knowledge of and is aware of the '428 patent. Pfizer otherwise denies the allegations of Paragraph 50. Pfizer admits that Genentech disclosed the '428 patent on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer's

proposed biosimilar Herceptin® product. Pfizer denies the remaining allegations of Paragraph 50.

51. Denied.

52. Denied.

53. Denied.

**COUNT THREE**

**(Infringement of the '415 Patent)**

54. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

55. Pfizer admits that United States Patent No. 6,331,415 ("the '415 patent") was issued by the United States Patent and Trademark Office ("PTO") on December 18, 2001. Pfizer admits that what Genentech purports to be a copy of the '415 patent was attached to the Complaint as Exhibit C. Pfizer denies the remaining allegations of Paragraph 55.

56. Pfizer admits that the '415 patent expired on December 18, 2018. Pfizer denies the remaining allegations of Paragraph 56.

57. Denied.

58. Denied.

59. Pfizer admits that if its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer admits that it manufactured some aBLA product before the expiry of the '415 patent that was solely for uses reasonably related to the development and submission of information to the FDA in connection with Pfizer's BLA. Pfizer's activities prior to the expiration of the '415 patent are protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1). Pfizer denies the remaining allegations of Paragraph 59.

60. Pfizer admits that it has knowledge of and is aware of the ’415 patent. Pfizer otherwise denies the allegations of Paragraph 60. Pfizer admits that U.S. Patent No. 7,449,616, to which Pfizer is listed as an assignee, cites to a U.S. Patent No. 6,331,415. Pfizer admits that Genentech disclosed the ’415 patent on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer’s proposed biosimilar Herceptin® product. Pfizer denies the remaining allegations of Paragraph 60.

61. Denied.

62. Denied.

63. Denied.

**COUNT FOUR**

**(Infringement of the ’213 Patent)**

64. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

65. Pfizer admits that United States Patent No. 6,407,213 (“the ’213 patent”) was issued by the United States Patent and Trademark Office (“PTO”) on June 18, 2002. Pfizer admits that what Genentech purports to be a copy of the ’213 patent was attached to the Complaint as Exhibit D. Pfizer denies the remaining allegations of Paragraph 65.

66. Admitted.

67. Denied.

68. Denied.

69. Denied.

70. Pfizer admits that Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin®. Pfizer denies the remaining allegations of Paragraph 70.

71. Denied.

72. Denied.

73. Pfizer admits that Genentech listed the ’213 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 73.

74. Denied.

75. Denied.

76. Denied.

**COUNT FIVE**

**(Declaratory Judgment of Infringement of the ’213 Patent)**

77. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

78. Denied.

79. Denied.

80. Denied.

81. Denied. The ’213 patent does not recite any method claims.

82. Denied.

83. Pfizer admits that Genentech listed the ’213 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 83.

84. Denied.

85. Admitted.

86. Admitted.

87. Denied.

**COUNT SIX**

**(Infringement of the ’516 Patent)**

88. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

89. Pfizer admits that United States Patent No. 6,610,516 ("the '516 patent") was issued by the United States Patent and Trademark Office ("PTO") on August 26, 2003. Pfizer admits that what Genentech purports to be a copy of the '516 patent was attached to the Complaint as Exhibit E. Pfizer denies the remaining allegations of Paragraph 89.

90. Admitted. Pfizer believes Genentech lacks a good-faith basis for asserting the '516 patent against Pfizer in connection with its aBLA No. 761099.

91. Denied.

92. Denied.

93. Denied.

94. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 94 and, therefore, denies the same.

95. Denied.

96. Denied.

97. Pfizer admits that Genentech listed the '516 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 97.

98. Denied.

99. Denied.

100. Denied.

**COUNT SEVEN**

**(Declaratory Judgment of Infringement of the '516 Patent)**

101. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

102. Denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Pfizer admits that Genentech listed the '516 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 107.

108. Denied.

109. Admitted.

110. Admitted.

111. Denied.

**COUNT EIGHT**

**(Infringement of the '879 Patent)**

112. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

113. Pfizer admits that United States Patent No. 6,884,879 ("the '879 patent") was issued by the United States Patent and Trademark Office ("PTO") on April 26, 2005. Pfizer admits that what Genentech purports to be a copy of the '879 patent was attached to the Complaint as Exhibit F. Pfizer denies the remaining allegations of Paragraph 113.

114. Pfizer admits that the '879 patent expired on April 7, 2017. Pfizer denies the remaining allegations of Paragraph 114.

115. Denied.

116. Denied.

117. Pfizer admits that if its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer admits that it manufactured some aBLA product before the expiry of the '879 patent that was solely for uses reasonably related to the development and submission of information to the FDA in connection with Pfizer's BLA. Pfizer's activities prior to the expiration of the '879 patent are protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1). Pfizer denies the remaining allegations of Paragraph 117.

118. Denied.

119. Pfizer admits that it has knowledge of and is aware of the '879 patent. Pfizer admits that Pfizer filed an *inter partes* review petition with the PTO challenging the validity of United States Patent No. 9,795,672. Pfizer otherwise denies the allegations of Paragraph 119.

120. Denied.

121. Denied.

122. Denied.

**COUNT NINE**

**(Infringement of the '269 Patent)**

123. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

124. Pfizer admits that United States Patent No. 7,060,269 ("the '269 patent") was issued by the United States Patent and Trademark Office ("PTO") on June 13, 2006. Pfizer admits that what Genentech purports to be a copy of the '269 patent was attached to the Complaint as Exhibit G. Pfizer denies the remaining allegations of Paragraph 124.

125. Admitted.

126. Pfizer admits that Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin®. The '269 patent will expire on July 4, 2019 before the date that Pfizer is permitted to begin commercial marketing based on the notice of commercial marketing that Pfizer provided to Genentech. Pfizer denies the remaining allegations of Paragraph 126.

127. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 127 and, therefore, denies the same.

128. Denied.

129. Admitted.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Pfizer admits that Genentech listed the '269 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 135.

136. Denied.

**COUNT TEN**

**(Declaratory Judgment of Infringement of the '269 Patent)**

137. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Pfizer admits that Genentech listed the '269 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 146.

147. Denied.

148. Admitted.

149. Admitted.

150. Denied.

**COUNT ELEVEN**

**(Infringement of the '901 Patent)**

151. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

152. Pfizer admits that United States Patent No. 7,169,901 ("the '901 patent") was issued by the United States Patent and Trademark Office ("PTO") on January 30, 2007. Pfizer admits that what Genentech purports to be a copy of the '901 patent was attached to the Complaint as Exhibit H. Pfizer denies the remaining allegations of Paragraph 152.

153. Admitted.

154. Denied.

155. Denied.

156. Denied.

157. Denied.

158. Pfizer admits that Genentech listed the '901 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 158.

159. Denied.

160. Denied.

161. Denied.

**COUNT TWELVE**

**(Infringement of the '660 Patent)**

162. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

163. Pfizer admits that United States Patent No. 7,390,660 ("the '660 patent") was issued by the United States Patent and Trademark Office ("PTO") on June 24, 2008. Pfizer admits that what Genentech purports to be a copy of the '660 patent was attached to the Complaint as Exhibit I. Pfizer denies the remaining allegations of Paragraph 163.

164. Admitted.

165. Denied.

166. Denied.

167. Denied.

168. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 168 and, therefore, denies the same.

169. Denied.

170. Denied.

171. Pfizer admits that Genentech listed the ’660 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 171.

172. Denied.

173. Denied.

174. Denied.

**COUNT THIRTEEN**

**(Declaratory Judgment of Infringement of the ’660 Patent)**

175. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

176. Denied.

177. Denied.

178. Denied.

179. Denied.

180. Denied.

181. Pfizer admits that Genentech listed the ’660 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 181.

182. Denied.

183. Admitted.

184. Admitted.

185. Denied.

**COUNT FOURTEEN**

**(Infringement of the ’704 Patent)**

186. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

187. Pfizer admits that United States Patent No. 7,485,704 ("the '704 patent") was issued by the United States Patent and Trademark Office ("PTO") on February 3, 2009. Pfizer admits that what Genentech purports to be a copy of the '704 patent was attached to the Complaint as Exhibit J. Pfizer denies the remaining allegations of Paragraph 187.

188. Admitted.

189. Denied.

190. Denied.

191. Denied.

192. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 192 and, therefore, denies the same.

193. Denied.

194. Denied.

195. Pfizer admits that Genentech listed the '704 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 195.

196. Denied.

197. Denied.

198. Denied.

**COUNT FIFTEEN**

**(Declaratory Judgment of Infringement of the '704 Patent)**

199. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

200. Denied.

201. Denied.

202. Denied.

203. Denied.

204. Denied.

205. Pfizer admits that Genentech listed the ’704 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 205.

206. Denied.

207. Admitted.

208. Admitted.

209. Denied.

**COUNT SIXTEEN**

**(Infringement of the ’115 Patent)**

210. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

211. Pfizer admits that United States Patent No. 7,622,115 (“the ’115 patent”) was issued by the United States Patent and Trademark Office (“PTO”) on November 24, 2009. Pfizer admits that what Genentech purports to be a copy of the ’115 patent was attached to the Complaint as Exhibit K. Pfizer denies the remaining allegations of Paragraph 211.

212. Admitted.

213. Pfizer admits that Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin®. Pfizer denies the remaining allegations of Paragraph 213.

214. Denied.

215. Denied.

216. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Pfizer admits that it intends to offer for sale and/or sell within the United States, or import into the United States, its aBLA product. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 216 and, therefore, denies the same.

217. Denied.

218. Denied.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

223. Pfizer admits that Pfizer's subsidiary Hospira, Inc. filed a petition for an inter partes review of the '115 patent (IPR2016-01771). Pfizer admits that Genentech listed the '115 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 223.

224. Denied.

**COUNT SEVENTEEN**

**(Declaratory Judgment of Infringement of the '115 Patent)**

225. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

226. Denied.

227. Denied.

228. Denied.

229. Denied.

230. Denied.

231. Denied.

232. Denied.

233. Denied.

234. Pfizer admits that Pfizer's subsidiary Hospira, Inc. filed a petition for an inter partes review of the '115 patent (IPR2016-01771). Pfizer admits that Genentech listed the '115 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 234.

235. Denied.

236. Admitted.

237. Admitted.

238. Denied.

**COUNT EIGHTEEN**

**(Infringement of the '799 Patent)**

239. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

240. Pfizer admits that United States Patent No. 7,807,799 ("the '799 patent") was issued by the United States Patent and Trademark Office ("PTO") on October 5, 2010. Pfizer admits that what Genentech purports to be a copy of the '799 patent was attached to the Complaint as Exhibit L. Pfizer denies the remaining allegations of Paragraph 240.

241. Admitted.

242. Denied.

243. Denied.

244. Denied.

245. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 245 and, therefore, denies the same.

246. Denied.

247. Denied.

248. Pfizer admits that Genentech listed the '799 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it had knowledge of the '799 patent in January, 2018. Pfizer denies the remaining allegations of Paragraph 248.

249. Denied.

250. Denied.

251. Denied.

**COUNT NINETEEN**

**(Declaratory Judgment of Infringement of the '799 Patent)**

252. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

253. Denied.

254. Denied.

255. Denied.

256. Denied.

257. Denied.

258. Pfizer admits that Genentech listed the '704 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 258.

259. Denied.

260. Admitted.

261. Admitted.

262. Denied.

**COUNT TWENTY**

**(Infringement of the ’336 Patent)**

263. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

264. Pfizer admits that United States Patent No. 7,846,336 (“the ’336 patent”) was issued by the United States Patent and Trademark Office (“PTO”) on December 7, 2010. Pfizer admits that what Genentech purports to be a copy of the ’336 patent was attached to the Complaint as Exhibit M. Pfizer denies the remaining allegations of Paragraph 264.

265. Admitted.

266. Denied.

267. Denied.

268. Denied.

269. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 269 and, therefore, denies the same.

270. Denied.

271. Denied.

272. Pfizer admits that Genentech listed the ’336 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 272.

273. Denied.

274. Denied.

275. Denied.

**COUNT TWENTY-ONE**

**(Declaratory Judgment of Infringement of the '336 Patent)**

276. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

277. Denied.

278. Denied.

279. Denied.

280. Denied.

281. Denied.

282. Pfizer admits that Genentech listed the '336 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 282.

283. Denied.

284. Admitted.

285. Admitted.

286. Denied.

**COUNT TWENTY-TWO**

**(Infringement of the '221 Patent)**

287. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

288. Pfizer admits that United States Patent No. 7,923,221 ("the '221 patent") was issued by the United States Patent and Trademark Office ("PTO") on April 12, 2011. Pfizer

admits that what Genentech purports to be a copy of the ’221 patent was attached to the Complaint as Exhibit N. Pfizer denies the remaining allegations of Paragraph 288.

289. Pfizer admits that the ’221 patent expired on December 18, 2018. Pfizer denies the remaining allegations of Paragraph 289.

290. Denied.

291. Denied.

292. Pfizer admits that if its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, but not before the date provided to Genentech in Pfizer’s statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer admits that it manufactured some aBLA product before the expiry of the ’221 patent that was solely for uses reasonably related to the development and submission of information to FDA in connection with Pfizer’s BLA. Pfizer’s activities prior to the expiration of the ’428 patent are protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1). Pfizer denies the remaining allegations of Paragraph 292.

293. Denied.

294. Pfizer admits that it has knowledge of and is aware of the ’221 patent. Pfizer admits that Genentech disclosed the ’221 patent on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer’s proposed biosimilar Herceptin® product. Pfizer denies the remaining allegations of Paragraph 294.

295. Denied.

296. Denied.

297. Denied.

**COUNT TWENTY-THREE**

**(Infringement of the ’225 Patent)**

298. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

299. Pfizer admits that United States Patent No. 8,314,225 ("the '225 patent") was issued by the United States Patent and Trademark Office ("PTO") on November 20, 2012. Pfizer admits that what Genentech purports to be a copy of the '225 patent was attached to the Complaint as Exhibit O. Pfizer denies the remaining allegations of Paragraph 299.

300. Admitted.

301. Denied.

302. Denied.

303. Denied.

304. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 304 and, therefore, denies the same.

305. Denied.

306. Denied.

307. Pfizer admits that Genentech listed the '225 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the '225 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 307.

308. Denied.

309. Denied.

310. Denied.

**COUNT TWENTY-FOUR**

**(Declaratory Judgment of Infringement of the '225 Patent)**

311. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

312. Denied.

313. Denied.

314. Denied.

315. Denied.

316. Denied.

317. Pfizer admits that Genentech listed the '225 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the '225 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 317.

318. Denied.

319. Admitted.

320. Admitted.

321. Denied.

**COUNT TWENTY-FIVE**

**(Infringement of the '983 Patent)**

322. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

323. Pfizer admits that United States Patent No. 8,512,983 ("the '983 patent") was issued by the United States Patent and Trademark Office ("PTO") on November 20, 2012. Pfizer admits that what Genentech purports to be a copy of the '983 patent was attached to the Complaint as Exhibit P. Pfizer denies the remaining allegations of Paragraph 323.

324. Admitted.

325. Denied.

326. Denied.

327. Denied.

328. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 328 and, therefore, denies the same.

329. Denied.

330. Denied.

331. Pfizer admits that Genentech listed the ’983 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the ’983 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 331.

332. Denied.

333. Denied.

334. Denied.

**COUNT TWENTY-SIX**

**(Declaratory Judgment of Infringement of the ’983 Patent)**

335. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

336. Denied.

337. Denied.

338. Denied.

339. Denied.

340. Denied.

341. Pfizer admits that Genentech listed the ’983 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the ’983 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 341.

342. Denied.

343. Admitted.

344. Admitted.

345. Denied.

**COUNT TWENTY-SEVEN**

**(Infringement of the ’869 Patent)**

346. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

347. Pfizer admits that United States Patent No. 8,574,869 (“the ’869 patent”) was issued by the United States Patent and Trademark Office (“PTO”) on November 5, 2013. Pfizer admits that what Genentech purports to be a copy of the ’869 patent was attached to the Complaint as Exhibit Q. Pfizer denies the remaining allegations of Paragraph 347.

348. Admitted.

349. Denied.

350. Denied.

351. Denied.

352. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 352 and, therefore, denies the same.

353. Denied.

354. Denied.

355. Pfizer admits that Genentech listed the ’869 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the ’869 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 355.

356. Denied.

357. Denied.

358. Denied.

**COUNT TWENTY-EIGHT**

**(Declaratory Judgment of Infringement of the ’869 Patent)**

359. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

360. Denied.

361. Denied.

362. Denied.

363. Denied.

364. Denied.

365. Pfizer admits that Genentech listed the ’869 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the ’869 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 365.

366. Denied.

367. Admitted.

368. Admitted.

369. Denied.

**COUNT TWENTY-NINE**

**(Infringement of the '035 Patent)**

370. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

371. Pfizer admits that United States Patent No. 9,441,035 ("the '035 patent") was issued by the United States Patent and Trademark Office ("PTO") on September 13, 2016. Pfizer admits that what Genentech purports to be a copy of the '035 patent was attached to the Complaint as Exhibit R. Pfizer denies the remaining allegations of Paragraph 371.

372. Admitted.

373. Denied.

374. Denied.

375. Denied.

376. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 376 and, therefore, denies the same.

377. Denied.

378. Denied.

379. Pfizer admits that Genentech listed the '035 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the '035 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 379.

380. Denied.

381. Denied.

382. Denied.

**COUNT THIRTY**

**(Declaratory Judgment of Infringement of the ’035 Patent)**

383. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

384. Denied.

385. Denied.

386. Denied.

387. Denied.

388. Denied.

389. Pfizer admits that Genentech listed the ’035 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the ’035 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 389.

390. Denied.

391. Admitted.

392. Admitted.

393. Denied.

**COUNT THIRTY-ONE**

**(Infringement of the ’293 Patent)**

394. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

395. Pfizer admits that United States Patent No. 9,714,293 (“the ’293 patent”) was issued by the United States Patent and Trademark Office (“PTO”) on July 25, 2017. Pfizer admits that what Genentech purports to be a copy of the ’293 patent was attached to the Complaint as Exhibit S. Pfizer denies the remaining allegations of Paragraph 395.

396. Admitted.

397. Denied.

398. Denied.

399. Denied.

400. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 400 and, therefore, denies the same.

401. Denied.

402. Denied.

403. Pfizer admits that Genentech listed the '293 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the '293 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 403.

404. Denied.

405. Denied.

406. Denied.

**COUNT THIRTY-TWO**

**(Declaratory Judgment of Infringement of the '293 Patent)**

407. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

408. Denied.

409. Denied.

410. Denied.

411. Denied.

412. Denied.

413. Pfizer admits that Genentech listed the '293 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that it was aware of the '293 patent in January 2018. Pfizer denies the remaining allegations of Paragraph 413.

414. Denied.

415. Admitted.

416. Admitted.

417. Denied.

**COUNT THIRTY-THREE**

**(Infringement of the '672 Patent)**

418. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

419. Pfizer admits that United States Patent No. 9,795,672 ("the '672 patent") was issued by the United States Patent and Trademark Office ("PTO") on October 24, 2017. Pfizer admits that what Genentech purports to be a copy of the '672 patent was attached to the Complaint as Exhibit T. Pfizer denies the remaining allegations of Paragraph 419.

420. Admitted.

421. Pfizer admits that Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin®. Pfizer denies the remaining allegations of Paragraph 421.

422. Denied.

423. Denied.

424. Admitted.

425. Denied.

426. Denied.

427. Denied.

428. Denied.

429. Denied.

430. Denied.

431. Pfizer admits that Pfizer filed a petition for *inter partes* review of the '672 patent (IPR2018-00373). Pfizer admits that Genentech listed the '672 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 431.

432. Denied.

**COUNT THIRTY-FOUR**

**(Declaratory Judgment of Infringement of the '672 Patent)**

433. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

434. Denied.

435. Denied.

436. Denied.

437. Denied.

438. Denied.

439. Denied.

440. Denied.

441. Denied.

442. Pfizer admits that Pfizer filed a petition for *inter partes* review of the '672 patent (IPR2018-00373). Pfizer admits that Genentech listed the '672 patent on its November 13, 2018

list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 442.

443. Denied.

444. Admitted.

445. Admitted.

446. Denied.

**COUNT THIRTY-FIVE**

**(Infringement of the '904 Patent)**

447. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

448. Pfizer admits that United States Patent No. 9,884,904 ("the '904 patent") was issued by the United States Patent and Trademark Office ("PTO") on February 6, 2018. Pfizer admits that what Genentech purports to be a copy of the '904 patent was attached to the Complaint as Exhibit U. Pfizer denies the remaining allegations of Paragraph 448.

449. Admitted.

450. Denied.

451. Denied.

452. Denied.

453. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 453 and, therefore, denies the same.

454. Denied.

455. Denied.

456. Pfizer admits that Genentech listed the '904 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 456.

457. Denied.

458. Denied.

459. Denied.

**COUNT THIRTY-SIX**

**(Declaratory Judgment of Infringement of the '904 Patent)**

460. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

461. Denied.

462. Denied.

463. Denied.

464. Denied.

465. Denied.

466. Pfizer admits that Genentech listed the '904 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 466.

467. Denied.

468. Admitted.

469. Admitted.

470. Denied.

**COUNT THIRTY-SEVEN**

**(Infringement of the '611 Patent)**

471. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

472. Pfizer admits that United States Patent No. 10,010,611 ("the '611 patent") was issued by the United States Patent and Trademark Office ("PTO") on July 3, 2018. Pfizer admits that what Genentech purports to be a copy of the '611 patent was attached to the Complaint as Exhibit V. Pfizer denies the remaining allegations of Paragraph 472.

473. Admitted.

474. Denied.

475. Denied.

476. Denied.

477. Pfizer admits that Pfizer provided a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) that permits Pfizer to begin commercial marketing as early as July 17, 2019. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 477 and, therefore, denies the same.

478. Denied.

479. Denied.

480. Pfizer admits that Genentech listed the '611 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 480.

481. Denied.

482. Denied.

483. Denied.

**COUNT THIRTY-EIGHT**

**(Declaratory Judgment of Infringement of the '611 Patent)**

484. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

485. Denied.

486. Denied.

487. Denied.

488. Denied.

489. Denied.

490. Pfizer admits that Genentech listed the '611 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer denies the remaining allegations of Paragraph 490.

491. Denied.

492. Admitted.

493. Admitted.

494. Denied.

**COUNT THIRTY-NINE**

**(Declaratory Judgment as to 42 U.S.C. § 2762(*l*)(9)(C))**

495. Pfizer incorporates by reference its answers to each of the preceding paragraphs as if fully set forth herein.

496. Pfizer admits only that Genentech purports to assert a claim pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, to which it is not entitled.

497. Admitted.

498. Pfizer admits that on September 14, 2018, Pfizer produced its BLA to Genentech, pursuant to 42 U.S.C. § 262(*l*)(2)(A). Pfizer's BLA contains over 565,000 pages of information on Pfizer's Product and the processes to manufacture it. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. To the extent that portions of Pfizer's aBLA were not produced, those portions are not relevant or necessary for Genentech to understand the process or processes used to manufacture Pfizer's product. Pfizer admits that

Genentech asked Pfizer to provide certain information in addition to its aBLA. Pfizer admits that it provided certain additional information to Genentech, despite having no requirement to do so, but refused to provide other information that Pfizer was not required to produce under 42 U.S.C. § 262(*l*)(2)(A). Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 498 and, therefore, denies the same.

499. Pfizer admits that on September 14, 2018, Pfizer produced its BLA to Genentech, pursuant to 42 U.S.C. § 262(*l*)(2)(A). Pfizer's BLA contains over 565,000 pages of information on Pfizer's Product and the processes to manufacture it. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. To the extent that portions of Pfizer's aBLA were not produced, those portions are not relevant or necessary for Genentech to understand the process or processes used to manufacture Pfizer's product. Pfizer admits that Genentech asked Pfizer to provide certain information in addition to its aBLA.

500. Pfizer admits that it took the position that its September 14, 2018 production satisfied its obligations under 42 U.S.C. § 262(*l*)(2)(A), which it did.

501. Pfizer admits that the Complaint purports to dispute that Pfizer's production of portions of its aBLA satisfied its obligations under 42 U.S.C. § 262(*l*)(2)(A).

502. Denied.

503. Denied.

**JURY TRIAL DEMANDED**

The Complaint requests a trial by jury, to which no response is required.

**PRAYER FOR RELIEF**

The remainder of the Complaint recites a prayer for relief for which no response is required. To the extent any response is required, Pfizer denies that Genentech is entitled to any remedy or relief.

**ADDITIONAL DENIAL**

To the extent that there are any allegations in the Complaint directed to Pfizer to which Pfizer did not respond specifically, such omission was inadvertent, and Pfizer hereby denies any such allegations.

**AFFIRMATIVE AND OTHER DEFENSES**

Without any admission as to the burden of proof, burden of persuasion, or truth of any allegation in the Complaint, Pfizer relies upon the following defenses:

**FIRST DEFENSE**

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

**SECOND DEFENSE**

Pfizer has complied with the provisions of the BPCIA, including specifically 42 U.S.C. § 262(*l*)(2)(A).

**THIRD DEFENSE**

All claims of the asserted patent are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq*., including without limitation §§ 101, 102, 103, 112 and/or any judicially-created doctrine of invalidity including obviousness-type double patenting.

**FOURTH DEFENSE**

All claims of one or more of the asserted patents are unenforceable at least due to inequitable conduct and/or prosecution laches.

**FIFTH DEFENSE**

The manufacture, use, offer for sale, sale, and/or importation into the United States of product described in BLA No. 761099 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any asserted patent directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

**SIXTH DEFENSE**

The filing of BLA No. 761099 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any asserted patent directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

**SEVENTH DEFENSE**

Genentech is not entitled to preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction that enjoins Pfizer, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with Pfizer and/or its successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any product that purportedly infringes, or the use or manufacture of which purportedly infringes any of the asserted patents.

**EIGHTH DEFENSE**

Pfizer's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 271(e)(4) or 35 U.S.C. § 285.

**NINTH DEFENSE**

Pfizer has not willfully infringed any claim of the asserted patents.

**TENTH DEFENSE**

Pfizer's activities fall within the safe harbor provision of 35 U.S.C. § 271(e)(1).

**ELEVENTH DEFENSE**

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

**TWELFTH DEFENSE**

Any additional defense or counterclaims that discovery may reveal.

**RESERVATION OF DEFENSES**

Pfizer reserves its right to assert any additional defenses or counterclaims, at law or equity, which may exist.

**PFIZER'S COUNTERCLAIMS**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Counterclaim Plaintiff Pfizer Inc. ("Pfizer") by and through its attorneys, hereby submits these Counterclaims against Counterclaim Defendants Genentech, Inc. ("Genentech"), City of Hope, and Hoffman-La Roche, Inc. ("Roche") (collectively, "Counterclaim Defendants").

1. These are Pfizer's Counterclaims for declaratory judgment of non-infringement and invalidity of one or more claims of the asserted patents under 35 U.S.C. § 271(e)(2)(C)(i), 28 U.S.C. §§ 2201 and 2202.

2. Pfizer repeats and incorporates by reference each of the foregoing Paragraphs of Pfizer's Answer and Affirmative Defenses to the Complaint.

**THE PARTIES**

3. Pfizer is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 235 East 42nd Street, New York, NY 10017.

4. On information and belief, Genentech is a corporation existing under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080.

5. On information and belief, City of Hope is a not-for-profit organization existing under the laws of California with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

6. On information and belief, Roche is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

7. As asserted in the Complaint, Roche is the owner of four of the patents asserted in this action – U.S. Patent Nos. 7,390,660, 7,846,336, 8,314,225, and 9,884,904. Disposing of this action in Roche's absence would, upon information and belief, impair or impede Roche's ability to protect its interest in the four patents and leave Pfizer with a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of Roche's interest in the asserted patents.

**JURISDICTION AND VENUE**

8. These counterclaims are for declaratory judgment of invalidity and non-infringement, which arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, pursuant to 28 U.S.C. §§ 2201 and 2202 for determining questions of actual controversy between the parties regarding the rights and other legal relations of the parties with respect to the Biosimilars Price Competition and Innovation Act (the "BPCIA").

9. This Court has subject matter jurisdiction over these counterclaims pursuant to 42 U.S.C. § 262(k)-(*l*), 28 U.S.C. §§ 1331, 1338(a) and 1367(a), and 35 U.S.C. § 271(e)(2)(C).

10. This Court has personal jurisdiction over each of Genentech, Inc. and City of Hope at least because they have subjected themselves to the jurisdiction of this Court in this case by filing the Complaint.

11. This Court has personal jurisdiction over Roche at least because Roche is the owner by assignment of four of the patents asserted in this action brought by its exclusive licensee Genentech, and because Roche has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted numerous patents in this jurisdiction, including, *inter alia*, in the matters of *Genentech, Inc. et al. v. Celltrion, Inc. et al.*, No. 18-cv-95; No. 18-cv-1025 (D. Del.); *Hoffman-La Roche Inc. et al. v. Aurobindo Pharma Limited et al.*, No. 14-cv-990 (D. Del.); *Warner Chilcott Company, et al. v. Teva Pharmaceuticals USA Inc.*, No. 08-cv-627 (D. Del.). Finally, upon information and belief, Hoffman-La Roche researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in Delaware and because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

12. Venue in this case is proper in this judicial district pursuant to 28 U.S.C. § 1391 and by virtue of Genentech's filing of this action in this Court.

**THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT**

13. In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the Biologics Price Competition and Innovation Act of 2009.

14. The BPCIA established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product (the "reference product"). The purpose of this law was to create a "biosimilars pathway balancing innovation and consumer interests."

15. The U.S. Food and Drug Administration ("FDA") traditionally approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a).

16. The BPCIA, by contrast and design, allows an applicant to file an abbreviated biologics license application to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." Thus, the BPCIA authorizes a biosimilar applicant to rely in part on the approved license of a reference product.

17. To balance innovation and price competition, Congress enacted the BPCIA to provide a four-year and a 12-year exclusivity period to a reference product, both beginning on the date of first licensure of the reference product. Specifically, approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to 12 years of exclusivity against follow-on products, regardless of patent protection.

18. In addition to the biosimilars pathway of 42 U.S.C. § 262(k), the BPCIA sets forth a procedure by which the biosimilar applicant and reference product sponsor may exchange information relating to potential patent disputes. *See* 42 U.S.C. § 262(*l*). These exchanges occur after the biosimilar BLA has been submitted to the FDA but before any court-enforced confidentiality protections are in place.

19. First, within 20 days after the FDA publishes a notice of acceptance for a 262(k) application, the applicant may provide a copy of the application to the reference product sponsor.

42 U.S.C. § 262(*l*)(2)(A). The BPCIA gives a biosimilar applicant the option either to share its biosimilar application with the reference product sponsor promptly after acceptance of the BLA by the FDA or to face the consequences provided by the BPCIA, specifically 42 U.S.C. § 262(*l*)(9)(C).

20. The BPCIA does not provide for injunctive relief, declaratory judgment of non-compliance or damages for failing to provide the disclosures pursuant to subsection (*l*)(2)(A). Instead, the BPCIA and/or 35 U.S.C. § 271(e)(4) precludes and preempts any and all such claims and remedies.

21. If the subsection (k) applicant chooses to provide its subsection (k) application to the reference product sponsor, the reference product sponsor may provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted . . ." not later than 60 days after receipt of the application. 42 U.S.C. § 262(*l*)(3)(A). The reference product sponsor may also identify which of the listed patents it would be willing to license to the subsection (k) applicant.

22. The subsection (k) applicant then has 60 days after receipt of the list pursuant to § 262(*l*)(3)(A) to provide "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application[.]" 42 U.S.C. § 262(*l*)(3)(B). The subsection (k) applicant may also provide a response regarding any patents that the reference product sponsor would be willing to license.

23. The reference product sponsor then has 60 days after receipt of the list pursuant to § 262(*l*)(3)(B) to provide "a detailed statement that describes, with respect to each patent

described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." 42 U.S.C. § 262(*l*)(3)(B).

24. After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant engage in "good faith negotiations" to agree on which, if any, patents listed under paragraph (3) to litigate. If the parties reach agreement, the reference product sponsor has 30 days to bring suit.

25. In addition, under certain circumstances, the subsection (k) applicant may provide notice of commercial marketing to the reference product sponsor.

## FACTUAL BACKGROUND

### A. Genentech's BLA for Avastin®

26. According to the FDA's "Purple Book," Genentech obtained a license from the FDA for Avastin® (bevacizumab) on February 26, 2004.

27. According to the current product label, Avastin® is indicated for the treatment of (1) metastatic colorectal cancer; (2) first-line non-squamous non-small cell lung cancer; (3) recurrent glioblastoma; (4) metastatic renal cell carcinoma; (5) persistent, recurrent, or metastatic cervical cancer; and (6) epithelial ovarian, fallopian tube, or peritoneal cancer.

28. Genentech has marketed and sold Avastin® since 2004. Therefore, under 42 U.S.C. § 262(k)(7), Amgen's 12-year exclusivity period for Avastin® has long since expired.

### B. Pfizer's BLA No. 761099

29. Pfizer is one of the world's premier biopharmaceutical companies. Pfizer applies science and global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development and manufacture of healthcare products. Pfizer's global portfolio includes medicines, vaccines and medical devices, as well as many of the world's best-known consumer healthcare products. Pfizer works across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Pfizer collaborates with healthcare providers, governments and local communities to support and expand access to reliable, affordable healthcare around the world.

30. Pfizer is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product PF-06439535 described in Pfizer's BLA No. 761099 ("Pfizer's BLA") submitted on June 29, 2018. The reference product to Pfizer's BLA is Avastin® (bevacizumab).

31. Now, Genentech seeks to delay Pfizer from marketing Pfizer's bevacizumab biosimilar, to extend Genentech's exclusivity even further beyond that contemplated by Congress in the BPCIA, and to delay patient access to a more affordable version of this drug.

**C. The Parties' Exchanges Under the BPCIA**

32. On August 28, 2018, the FDA accepted Pfizer's BLA for review. On August 30, 2018, Pfizer sent a letter to Genentech notifying them that the FDA has accepted Pfizer's BLA for review. On September 14, 2018, within 20 days of the FDA's notice and in full compliance with 42 U.S.C. § 262(*l*)(2)(A), Pfizer provided Genentech with Pfizer's BLA, which included over 565,000 pages of information on Pfizer's Product and the processes used to manufacture it. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA.

33. On November 13, 2018, Genentech provided to Pfizer its list of patents purportedly pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("Genentech's 3A List").

34. On December 21, 2018, Pfizer provided its detailed statement that describes, on a claim by claim basis, the factual and legal basis for its opinion that each of the patents listed in Genentech's 3A List is invalid, unenforceable, and/or will not be infringed by the biological product that is the subject of Pfizer's BLA pursuant to 42 U.S.C. § 262(*l*)(3)(B) ("Pfizer's 3B Statement"). Thus, Pfizer fully complied with the BPCIA patent information exchange provisions. Also on December 21, 2018, Pfizer provided additional information about its manufacturing process in response to a request from Genentech, despite having no obligation to do so.

35. On January 18, 2019, Pfizer notified Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it intends to commence commercial marketing of PF-06439535 in the United States 180 days from the date of the notice.

36. On February 19, 2019, Genentech purported to provide Pfizer a statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's 3C Statement"), which did not meet the provisions of § 262(*l*)(3)(B)(ii)(I). Genentech's 3(C) Statement did not include sufficient information for at least certain patents to satisfy the requirements to provide the "the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed" and "a response to the [Pfizer's] statement concerning validity and enforceability."

37. On March 6, 2019, Pfizer sent Genentech a letter agreeing that the seventeen patents in Genentech's 3(C) Statement would be the subject of an action for patent infringement and stating that the agreement concluded negotiations under the BPCIA.

**THE PATENTS IN SUIT**

38. U.S. Patent No. 6,054,297 (the "'297 patent") is titled "Humanized Antibodies and Methods For Making Them" and lists Paul J. Carter and Leonard G. Presta as the inventors. The '297 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '297 patent.

39. U.S. Patent No. 6,121,428 (the "'428 patent") is titled "Protein Recovery" and lists Gregory S. Blank, Daljit S. Narindray, and Gerardo A. Zapata as the inventors. The '428 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '428 patent.

40. U.S. Patent No. 6,331,415 (the "'415 patent") is titled "Methods of Producing Immunoglobulins, Vectors, and Transformed Hosts Cells for Use Therein" and lists Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as the inventors. The '415 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech and City of Hope are co-owners by assignment of the '415 patent.

41. U.S. Patent No. 6,407,213 (the "'213 patent") is titled "Method for Making Humanized Antibodies" and lists Paul J. Carter and Leonard G. Presta as the inventors. The '213 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '213 patent.

42. U.S. Patent No. 6,610,516 (the "'516 patent") is titled "Cell Culture Process" and lists Dana C. Andersen, Tiffany M. Bridges, Martin Gawlitzek, and Cynthia A. Hoy as the inventors. The '516 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '516 patent.

43. U.S. Patent No. 6,884,879 (the "'879 patent") is titled "Anti-VEGF Antibodies" and lists Manuel Baca and James A. Wells as the inventors. The '879 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '879 patent.

44. U.S. Patent No. 7,060,269 (the "'269 patent") is titled "Anti-VEGF Antibodies" and lists Manuel Baca, James A. Wells, Leonard G. Presta, Henry B. Lowman, and Yvonne Man-yee Chen as the inventors. The '269 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '269 patent.

45. U.S. Patent No. 7,169,901 (the "'901 patent") is titled "Anti-VEGF Antibodies" and lists Manuel Baca, James A. Wells, Leonard G. Presta, Henry B. Lowman, and Yvonne Man-yee Chen as the inventors. The '901 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the '901 patent.

46. U.S. Patent No. 7,390,660 (the "'660 patent") is titled "Methods for Growing Mammalian Cells In Vitro" and lists Ulrich Behrendt, Horst Eberhardt, and Berthold Szperalski as the inventors. The '660 patent is assigned on its face to Hoffman-La Roche. According to the Complaint, the '660 patent is assigned to Hoffman-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '660 patent. Roche previously asserted U.S. Patent No. 7,390,660 in *Genentech, Inc. et al. v. Celltrion, Inc. et al.*, No. 18-cv-95; No. 18-cv-1025 (D. Del.).

47. U.S. Patent No. 7,485,704 (the "'704 patent") is titled "Reducing Protein A Leaching During Protein A Affinity Chromatography" and lists Robert L. Fahrner, Amy Laverdiere, Paul J. McDonald, and Rhona M. O'Leary as the inventors. The '704 patent is

assigned on its face to Genentech Inc. According to the Complaint, Genentech is the owner by assignment of the ’704 patent.

48. U.S. Patent No. 7,622,115 (the “’115 patent”) is titled “Treatment with Anti-VEGF Antibodies” and lists Gwendolyn Fyfe, Eric Holmgren, Robert D. Mass, and William Novotny as the inventors. The ’115 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’115 patent. In IPR2016-01771, the Patent Trial and Appeal Board (“PTAB”) found all claims of the ’115 patent unpatentable as obvious under 35 U.S.C. § 103.

49. U.S. Patent No. 7,807,799 (the “’799 patent”) is titled “Reducing Protein A Leaching During Protein A Affinity Chromatography” and lists Robert L. Fahrner, Amy Laverdiere, Paul J. McDonald, and Rhona M. O’Leary as the inventors. The ’799 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’799 Patent. In IPR2016-01837, the PTAB found claims 1, 2, and 5 of the ’799 patent unpatentable as anticipated under 35 U.S.C. § 102 and claims 1-3 and 5-11 of the ’799 patent unpatentable as obvious under 35 U.S.C. § 103.

50. U.S. Patent No. 7,846,336 (the “’336 patent”) is titled “Chromatographic Methods” and lists Josef Burg, Klaus Reichert, Axel Schroth, Hartmut Schurig, and Axel Wessner as the inventors. The ’336 patent is assigned on its face to Hoffman-La Roche, Inc. According to the Complaint, the ’336 patent is assigned to Hoffman-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the ’336 patent.

51. U.S. Patent No. 7,923,221 (the “’221 patent”) is titled “Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen” and lists Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as the

inventors. The ’221 patent is assigned on its face to Genentech, Inc. and City of Hope. According to the Complaint, Genentech and City of Hope are co-owners by assignment of the ’221 patent.

52. U.S. Patent No. 8,314,225 (the “’225 patent”) is titled “Heavy Chain Mutant Leading to Improved Immunoglobulin Production” and lists Ulrich Goepfert, Silke Hansen, Hendrik Knoetgen, Erhard Kopetzki, and Oliver Ploettner as the inventors. The ’225 patent is assigned on its face to Hoffman-La Roche Inc. According to the Complaint, the ’225 patent is assigned to Hoffman-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the ’225 patent. In IPR2018-01219, which concerns the ’225 patent, Roche has stated in its Mandatory Notices pursuant to 37 C.F.R. § 42.8(b) that it is the real party-in-interest and that Genentech is also a real party-in-interest.

53. U.S. Patent No. 8,512,983 (the “’983 patent”) is titled “Production of Proteins in Glutamine-Free Cell Culture Media” and lists Martin Gawlitzek, Shun Luo, and Christina Teresa Petraglia as the inventors. The ’983 patent is not assigned to any entity on its face. According to the Complaint, Genentech is the owner by assignment of the ’983 patent.

54. U.S. Patent No. 8,574,869 (the “’869 patent”) is titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides” and lists Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt as the inventors. The ’869 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’869 patent.

55. U.S. Patent No. 9,441,035 (the “’035 patent”) is titled “Cell Culture Media and Methods of Antibody Production” and lists Veronica Carvalhal, Natarahan Vijarasankaran, Lauren Brown, Thomas DiRocco, and Nathan McKnight as the inventors. The ’035 patent is

assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’035 patent.

56. U.S. Patent No. 9,714,293 (the “’293 patent”) is titled “Production of Proteins in Glutamine-Free Cell Culture Media” and lists Martin Gawlitzek, Sun Luo, and Christina Teresa Bevilacqua as the inventors. The ’293 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’293 patent.

57. U.S. Patent No. 9,795,672 (the “’672 patent”) is titled “Treatment with Anti-VEGF Antibodies” and lists Gwendolyn Fyfe, Eric Holmgren, and William Novotny as the inventors. The ’672 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’672 patent.

58. U.S. Patent No. 9,884,904 (the “’904 patent”) is titled “Method for Purifying Polypeptide Solutions” and lists Vinzenz Binder, Christina Hakemeyer, and Felizitas Schwarz as the inventors. The ’904 patent is assigned on its face to Hoffman-La Roche, Inc. According to the Complaint, the ’904 patent is assigned to Hoffman-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the ’904 patent.

59. U.S. Patent No. 10,010,611 (the “’611 patent”) is titled “Antibody Formulations” and lists Yatin Gokarn, Isidro E. Zarraga, Jonathan Zarzar, and Thomas Patapoff as the inventors. The ’611 patent is assigned on its face to Genentech, Inc. According to the Complaint, Genentech is the owner by assignment of the ’611 patent.

**COUNT ONE**
**Declaratory Judgment of Invalidity of U.S. Patent No. 6,054,297**

60. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 59 of the Counterclaims above.

61. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,054,297, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,054,297.

62. The claims of U.S. Patent No. 6,054,297 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting.

63. The alleged invention of U.S. Patent No. 6,054,297 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

64. The alleged invention of U.S. Patent No. 6,054,297 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

65. U.S. Patent No. 6,054,297 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

66. The alleged invention of U.S. Patent No. 6,054,297 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,054,297 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,054,297 and would have had a reasonable expectation of success in doing so.

67. The subject matter claimed in U.S. Patent No. 6,054,297 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

68. U.S. Patent No. 6,054,297 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

69. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,054,297 are invalid.

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

**COUNT TWO**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 6,054,297**

71. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 70 of the Counterclaims above.

72. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,054,297 either directly or indirectly, and either literally or under the doctrine of equivalents.

73. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,054,297 either literally or under the doctrine of equivalents and is not liable for such infringement.

74. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,054,297 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,054,297.

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

76. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,054,297. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT THREE**
**Declaratory Judgment of Invalidity of U.S. Patent No. 6,121,428**

77. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 76 of the Counterclaims above.

78. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,121,428, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,121,428.

79. The claims of U.S. Patent No. 6,121,428 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

80. U.S. Patent No. 6,121,428 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

81. The alleged invention of U.S. Patent No. 6,121,428 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,121,428 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,121,428 and would have had a reasonable expectation of success in doing so.

82. The subject matter claimed in U.S. Patent No. 6,121,428 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

83. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,121,428 are invalid.

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

**COUNT FOUR**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 6,121,428**

85. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 84 of the Counterclaims above.

86. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,121,428 either directly or indirectly, and either literally or under the doctrine of equivalents.

87. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,121,428 either literally or under the doctrine of equivalents and is not liable for such infringement.

88. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,121,428 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,121,428.

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

90. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,121,428.

Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT FIVE**
**Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415**

91. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 90 of the Counterclaims above.

92. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,331,415, based on Genentech's allegation in its Complaint that Pfizer has infringed U.S. Patent No. 6,331,415.

93. The claims of U.S. Patent No. 6,331,415 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

94. The alleged invention of U.S. Patent No. 6,331,415 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

95. The alleged invention of U.S. Patent No. 6,331,415 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

96. U.S. Patent No. 6,331,415 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

97. The alleged invention of U.S. Patent No. 6,331,415 does nothing more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,331,415 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,331,415 and would have had a reasonable expectation of success in doing so.

98. The subject matter claimed in U.S. Patent No. 6,331,415 fails to comply with 35 U.S.C. § 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

99. U.S. Patent No. 6,331,415 does not contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

100. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,331,415 are invalid.

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

**COUNT SIX**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 6,331,415**

102. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 102 of the Counterclaims above.

103. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,331,415 either directly or indirectly, and either literally or under the doctrine of equivalents.

104. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,331,415 either literally or under the doctrine of equivalents and is not liable for such infringement.

105. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,331,415 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,331,415.

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

107. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,331,415.

Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT SEVEN**
**Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213**

108. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 107 of the Counterclaims above.

109. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,407,213, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,407,213.

110. The claims of U.S. Patent No. 6,407,213 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting.

111. The alleged invention of U.S. Patent No. 6,407,213 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

112. The alleged invention of U.S. Patent No. 6,407,213 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

113. U.S. Patent No. 6,407,213 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

114. The alleged invention of U.S. Patent No. 6,407,213 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,407,213 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,407,213 and would have had a reasonable expectation of success in doing so.

115. The subject matter claimed in U.S. Patent No. 6,407,213 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

116. U.S. Patent No. 6,407,213 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

117. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,407,213 are invalid.

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

**COUNT EIGHT**
**Declaratory Judgment of Unenforceability of U.S. Patent No. 6,407,213**

119. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 118 of the Counterclaims above.

120. During the prosecution of the U.S. Patent No. 6,407,213, Genentech made misrepresentations and omissions in filings with the U.S. Patent and Trademark Office[1] ("Patent Office") material to patentability and did so with the specific intent to mislead or deceive the Patent Office.

121. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 (the "'101 patent") to the Patent Office to overcome a rejection based on that reference. Genentech told the Examiner that the '101 patent does not use the Kabat numbering system, despite the fact that the '101 patent expressly states that the Kabat numbering system is used for certain disclosed sequences.

122. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions at specific locations, including "93H." (*See* November 17, 1993 Claims at 109-110.)

123. On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting various pending claims as obvious under § 103 over EP 0239400, Queen 1989, and Riechmann 1988. (*See* December 9, 1994 Non-Final Rejection at 4.)

124. On June 12, 1995, Genentech amended the pending claims and deleted references to various substitutions, including a substitution at amino acid position "93H." (*See* June 12, 1995 Amendment at 3-4.)

[1] The filings are signed by patent counsel for Genentech, Ms. Wendy M. Lee (Reg. No. 40,378).

125. On December 19, 1996, the Examiner issued a Non-Final Rejection, rejecting various pending claims as anticipated by the ’101 Patent. (*See* December 19, 1996 Non-Final Rejection at 7-8.)

126. In a Supplemental Amendment dated October 6, 1997, signed by Ms. Wendy M. Lee, Genentech argued that Queen 1989 and the ’101 patent were distinguishable because they “use sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues.” (October 6, 1997 Supplemental Amendment at 6.)

127. In a Supplemental Amendment dated January 15, 1999, Genentech included a substitution at residue 93H in new claim 115 and claims dependent therefrom. (*See* January 15, 1999 Supplemental Amendment at 8.)

128. On October 25, 2000, the Examiner issued a Non-Final Rejection, rejecting claims 115-117, 123, and 127, which included the 93H substitution, as anticipated by the ’101 Patent because the Examiner understood the ’101 Patent to disclose a substitution at 93H according to the Kabat numbering system. (*See* October 25, 2000 Non-Final Rejection at 7.)

129. In an Amendment dated April 25, 2001, signed by Ms. Lee, Genentech distinguished the ’101 patent, arguing that the ’101 patent uses a different numbering system and, in particular, does not disclose a substitution at 93H using the Kabat system:

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the ’101 patent] is not 93H ‘utilizing the numbering system set forth in Kabat’ (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and

> 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

(April 25, 2001 Amendment at 7.)

130. On December 11, 2001, the Examiner indicated during an interview that the pending claims, including claims 115-117, 123 and 127, were allowable. (*See* December 11, 2001 Examiner Interview Summary Record at 1.)

131. Contrary to Genentech's representations to the Patent Office that the '101 patent does not use the Kabat numbering system, the '101 patent expressly states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." ('101 patent at 8:15-18.) The '101 patent also expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93H. (*Id.* at 15:17-37.) Moreover, Table 5 of the '101 patent identifies residue "H93," and expressly states that "[t]he amino acid residues are numbered according to the Kabat system":

TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

| Residue No.[1] | Amino Acid | Contacting CDR residues[2] |
|---|---|---|
| Fd79 | | |
| L49 | Lys | L50Y, L53N, L55E, H99D, H100Y |
| H93 | Leu | H35S, H37V, H100CF |
| Fd138-80 | | |
| L36 | His | L34V, L89Q |
| H27 | Tyr | H32H, H34I |
| H30 | Tyr | H32H, H53R |
| H48 | Phe | H63F |
| H66 | Lys | H63F |
| H67 | Ala | H63F |

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

132. Additionally, the sequence in Figure 30A of the ’101 Patent, which shows a substitution at 93H, is numbered according to the Kabat system:

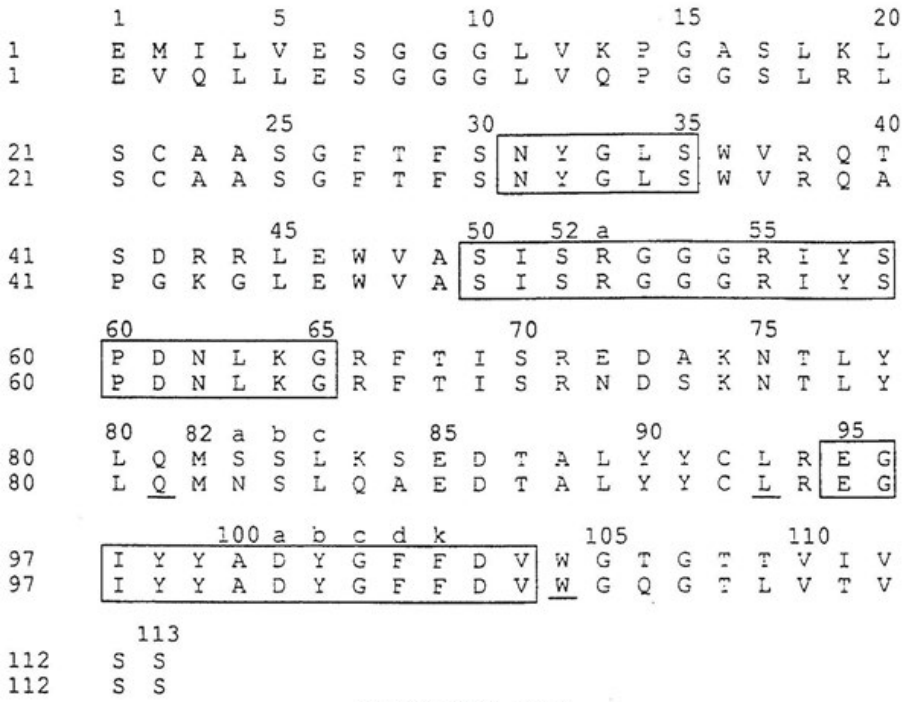


FIGURE 30A

And the sequences in Figures 2B, 6B, and 40 B, which use sequential numbering, show a substitution at 97H that corresponds to 93H in the Kabat numbering system.

133. Genentech misrepresented to the Examiner that the ’101 patent used sequential numbering, while arguing that the “claims of the instant application use Kabat numbering for the framework region residues,” to overcome the pending § 102 rejection based on the ’101 patent. In particular, Genentech misrepresented to the Examiner that “the substituted 93 FR residue in the [’101 patent] is not 93H ‘utilizing the numbering system set forth in Kabat,’” despite the express teaching in the ’101 Patent of a substitution at 93H using the Kabat system. Deceptive intent by Genentech is the single most reasonable inference to be drawn in light of the fact that the ’101 patent discloses sequences numbered according to the Kabat system and expressly describes a substitution at 93H using the Kabat system.

134. The Examiner had no reason to withdraw the § 102 rejection over the ’101 patent of claims reciting the 93H substitution, absent Genentech’s false and misleading representations. Genentech provided no other arguments to distinguish the ’101 patent from the claimed subject matter of claims 115-117, 123, and 127 in its April 26, 2001 Amendment. (*See* April 26, 2001 Amendment at 7-8.)

135. There is a real, substantial, and justiciable controversy between Pfizer and Genentech concerning whether the claims of the ’213 patent are enforceable in view of Genentech’s inequitable conduct before the Patent Office.

136. Pfizer is entitled to a judicial declaration that all claims of the ’213 patent are unenforceable.

**COUNT NINE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 6,407,213**

137. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 136 of the Counterclaims above.

138. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,407,213 either directly or indirectly, and either literally or under the doctrine of equivalents.

139. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,407,213 either literally or under the doctrine of equivalents and is not liable for such infringement.

140. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,407,213 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,407,213.

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

**COUNT TEN**
**Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516**

142. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 141 of the Counterclaims above.

143. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,610,516, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,610,516.

144. The claims of U.S. Patent No. 6,610,516 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

145. The alleged invention of U.S. Patent No. 6,610,516 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

146. The alleged invention of U.S. Patent No. 6,610,516 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

147. U.S. Patent No. 6,610,516 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

148. The alleged invention of U.S. Patent No. 6,610,516 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,610,516 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,610,516 and would have had a reasonable expectation of success in doing so.

149. The subject matter claimed in U.S. Patent No. 6,610,516 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

150. U.S. Patent No. 6,610,516 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

151. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,610,516 are invalid.

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

**COUNT ELEVEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 6,610,516**

153. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 152 of the Counterclaims above.

154. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,610,516 either directly or indirectly, and either literally or under the doctrine of equivalents.

155. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,610,516 either literally or under the doctrine of equivalents and is not liable for such infringement.

156. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,610,516 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,610,516.

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

158. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,610,516. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT TWELVE**
**Declaratory Judgment of Invalidity of U.S. Patent No. 6,884,879**

159. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 158 of the Counterclaims above.

160. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,884,879, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,884,879.

161. The claims of U.S. Patent No. 6,884,879 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting.

162. The alleged invention of U.S. Patent No. 6,884,879 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

163. The alleged invention of U.S. Patent No. 6,884,879 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

164. U.S. Patent No. 6,884,879 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

165. The alleged invention of U.S. Patent No. 6,884,879 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,884,879 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,884,879 and would have had a reasonable expectation of success in doing so.

166. The subject matter claimed in U.S. Patent No. 6,884,879 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

167. U.S. Patent No. 6,884,879 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

168. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,884,879 are invalid.

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

**COUNT THIRTEEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 6,884,879**

170. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 169 of the Counterclaims above.

171. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,884,879 either directly or indirectly, and either literally or under the doctrine of equivalents.

172. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,884,879 either literally or under the doctrine of equivalents and is not liable for such infringement.

173. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,884,879 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,884,879.

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

175. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,884,879. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT FOURTEEN**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,060,269**

176. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 175 of the Counterclaims above.

177. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,060,269, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,060,269.

178. The claims of U.S. Patent No. 7,060,269 are invalid for failure to satisfy one or more productions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and/or 103, and/or under the doctrine of obviousness-type double patenting.

179. The alleged invention of U.S. Patent No. 7,060,269 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

180. The alleged invention of U.S. Patent No. 7,060,269 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

181. U.S. Patent No. 7,060,269 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

182. The alleged invention of U.S. Patent No. 7,060,269 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,060,269 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,060,269 and would have had a reasonable expectation of success in doing so.

183. The subject matter claimed in U.S. Patent No. 7,060,269 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

184. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,060,269 are invalid.

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

**COUNT FIFTEEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,060,269**

186. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 185 of the Counterclaims above.

187. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,060,269 either directly or indirectly, and either literally or under the doctrine of equivalents.

188. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,060,269 either literally or under the doctrine of equivalents and is not liable for such infringement. U.S. Patent No. 7,060,269 will expire on July 4, 2019, before the date that Pfizer is permitted to begin commercial marketing based on the notice of commercial marketing that Pfizer provided to Genentech.

189. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,060,269 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,060,269.

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

**COUNT SIXTEEN**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,169,901**

191. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 190 of the Counterclaims above.

192. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,169,901, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,169,901.

193. The claims of U.S. Patent No. 7,169,901 are invalid for failure to satisfy one or more productions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112, and/or under the doctrine of obviousness-type double patenting.

194. The alleged invention of U.S. Patent No. 7,169,901 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

195. The alleged invention of U.S. Patent No. 7,169,901 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

196. U.S. Patent No. 7,169,901 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

197. The alleged invention of U.S. Patent No. 7,169,901 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,169,901 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,169,901 and would have had a reasonable expectation of success in doing so.

198. The subject matter claimed in U.S. Patent No. 7,169,901 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the

prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

199. U.S. Patent No. 7,169,901 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

200. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,169,901 are invalid.

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

**COUNT SEVENTEEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,169,901**

202. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 201 of the Counterclaims above.

203. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,169,901 either directly or indirectly, and either literally or under the doctrine of equivalents.

204. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,169,901 either literally or under the doctrine of equivalents and is not liable for such infringement.

205. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,169,901 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,169,901.

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

**COUNT EIGHTEEN**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,390,660**

207. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 206 of the Counterclaims above.

208. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,390,660, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,390,660.

209. The claims of U.S. Patent No. 7,390,660 are invalid for failure to satisfy one or more productions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and/or 103.

210. The alleged invention of U.S. Patent No. 7,390,660 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

211. The alleged invention of U.S. Patent No. 7,390,660 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

212. U.S. Patent No. 7,390,660 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

213. The alleged invention of U.S. Patent No. 7,390,660 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,390,660 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,390,660 and would have had a reasonable expectation of success in doing so.

214. The subject matter claimed in U.S. Patent No. 7,390,660 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

215. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,390,660 are invalid.

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

**COUNT NINETEEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,390,660**

217. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 216 of the Counterclaims above.

218. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,390,660 either directly or indirectly, and either literally or under the doctrine of equivalents.

219. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,390,660 either literally or under the doctrine of equivalents and is not liable for such infringement.

220. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,390,660 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,390,660.

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

222. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,884,879. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT TWENTY**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,485,704**

223. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 222 of the Counterclaims above.

224. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,485,704, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,485,704.

225. The claims of U.S. Patent No. 7,485,704 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101 and 103.

226. The alleged invention of U.S. Patent No. 7,485,704 is a natural phenomenon or law in combination with conventional steps. The conventional steps of the alleged invention do not transform the alleged invention as a whole into patent-eligible subject matter.

227. U.S. Patent No. 7,485,704 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

228. The alleged invention of U.S. Patent No. 7,485,704 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged

improvement over the prior art set forth in U.S. Patent No. 7,485,704 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,485,704 and would have had a reasonable expectation of success in doing so.

229. The subject matter claimed in U.S. Patent No. 7,485,704 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

230. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,485,704 are invalid.

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

**COUNT TWENTY-ONE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,485,704**

232. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 231 of the Counterclaims above.

233. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,485,704 either directly or indirectly, and either literally or under the doctrine of equivalents.

234. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,485,704 either literally or under the doctrine of equivalents and is not liable for such infringement.

235. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,485,704 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,485,704.

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

237. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,485,704. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT TWENTY-TWO**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,622,115**

238. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 237 of the Counterclaims above.

239. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,622,115, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,622,115.

240. The claims of U.S. Patent No. 7,622,115 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

241. The alleged invention of U.S. Patent No. 7,622,115 is a natural phenomenon or law in combination with conventional steps. The conventional steps of the alleged invention do not transform the alleged invention as a whole into patent-eligible subject matter.

242. The alleged invention of U.S. Patent No. 7,622,115 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

243. The alleged invention of U.S. Patent No. 7,622,115 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

244. U.S. Patent No. 7,622,115 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

245. The alleged invention of U.S. Patent No. 7,622,115 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,622,115 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,622,115 and would have had a reasonable expectation of success in doing so.

246. The subject matter claimed in U.S. Patent No. 7,622,115 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

247. U.S. Patent No. 7,622,115 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

248. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,622,115 are invalid.

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

**COUNT TWENTY-THREE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,622,115**

250. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 249 of the Counterclaims above.

251. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,622,115 either directly or indirectly, and either literally or under the doctrine of equivalents.

252. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,622,115 either literally or under the doctrine of equivalents and is not liable for such infringement.

253. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,622,115 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,622,115.

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

**COUNT TWENTY-FOUR**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799**

255. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 254 of the Counterclaims above.

256. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,807,799, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,807,799.

257. The claims of U.S. Patent No. 7,807,799 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102 and/or 103.

258. The alleged invention of U.S. Patent No. 7,807,799 is a natural phenomenon or law in combination with conventional steps. The conventional steps of the alleged invention do not transform the alleged invention as a whole into patent-eligible subject matter.

259. The alleged invention of U.S. Patent No. 7,807,799 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

260. The alleged invention of U.S. Patent No. 7,807,799 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

261. U.S. Patent No. 7,807,799 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

262. The alleged invention of U.S. Patent No. 7,807,799 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,807,799 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,807,799 and would have had a reasonable expectation of success in doing so.

263. The subject matter claimed in U.S. Patent No. 7,807,799 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the

prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

264. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,807,799 are invalid.

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

**COUNT TWENTY-FIVE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,807,799**

266. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 265 of the Counterclaims above.

267. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,807,799 either directly or indirectly, and either literally or under the doctrine of equivalents.

268. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,807,799 either literally or under the doctrine of equivalents and is not liable for such infringement.

269. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,807,799 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not

infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,807,799.

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

271. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,807,799. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT TWENTY-SIX**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,846,336**

272. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 271 of the Counterclaims above.

273. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,846,336, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,846,336.

274. The claims of U.S. Patent No. 7,846,336 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

275. U.S. Patent No. 7,846,336 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

276. The alleged invention of U.S. Patent No. 7,846,336 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,846,336 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,846,336 and would have had a reasonable expectation of success in doing so.

277. The subject matter claimed in U.S. Patent No. 7,846,336 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

278. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,846,336 are invalid.

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

280. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,846,336. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT TWENTY-SEVEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,846,336**

281. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 280 of the Counterclaims above.

282. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,846,336 either directly or indirectly, and either literally or under the doctrine of equivalents.

283. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,846,336 either literally or under the doctrine of equivalents and is not liable for such infringement.

284. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,846,336 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,846,336.

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

**COUNT TWENTY-EIGHT**
**Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221**

286. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 285 of the Counterclaims above.

287. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,923,221, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,923,221.

288. The claims of U.S. Patent No. 7,923,221 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

289. The alleged invention of U.S. Patent No. 7,923,221 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

290. The alleged invention of U.S. Patent No. 7,923,221 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

291. U.S. Patent No. 7,923,221 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

292. The alleged invention of U.S. Patent No. 7,923,221 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,923,221 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,923,221 and would have had a reasonable expectation of success in doing so.

293. The subject matter claimed in U.S. Patent No. 7,923,221 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

294. U.S. Patent No. 7,923,221 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

295. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,923,221 are invalid.

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

**COUNT TWENTY-NINE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 7,923,221**

297. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 296 of the Counterclaims above.

298. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,923,221 either directly or indirectly, and either literally or under the doctrine of equivalents.

299. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,923,221 either literally or under the doctrine of equivalents and is not liable for such infringement.

300. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,923,221 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,923,221.

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

302. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,923,221. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT THIRTY**
**Declaratory Judgment of Invalidity of U.S. Patent No. 8,314,225**

303. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 302 of the Counterclaims above.

304. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,314,225, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,314,225.

305. The claims of U.S. Patent No. 8,314,225 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

306. The alleged invention of U.S. Patent No. 8,314,225 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

307. The alleged invention of U.S. Patent No. 8,314,225 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

308. U.S. Patent No. 8,314,225 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

309. The alleged invention of U.S. Patent No. 8,314,225 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,314,225 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,314,225 and would have had a reasonable expectation of success in doing so.

310. The subject matter claimed in U.S. Patent No. 8,314,225 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

311. U.S. Patent No. 8,314,225 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

312. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,314,225 are invalid.

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

**COUNT THIRTY-ONE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 8,314,225**

314. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 313 of the Counterclaims above.

315. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,314,225 either directly or indirectly, and either literally or under the doctrine of equivalents.

316. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,314,225 either literally or under the doctrine of equivalents and is not liable for such infringement.

317. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,314,225 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,314,225.

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

**COUNT THIRTY-TWO**
**Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983**

319. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 318 of the Counterclaims above.

320. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,512,983, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,512,983.

321. The claims of U.S. Patent No. 8,512,983 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and/or 103.

322. The alleged invention of U.S. Patent No. 8,512,983 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

323. The alleged invention of U.S. Patent No. 8,512,983 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

324. U.S. Patent No. 8,512,983 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

325. The alleged invention of U.S. Patent No. 8,512,983 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,512,983 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,512,983 and would have had a reasonable expectation of success in doing so.

326. The subject matter claimed in U.S. Patent No. 8,512,983 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the

prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

327. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,512,983 are invalid.

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

**COUNT THIRTY-THREE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 8,512,983**

329. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 328 of the Counterclaims above.

330. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,512,983 either directly or indirectly, and either literally or under the doctrine of equivalents.

331. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,512,983 either literally or under the doctrine of equivalents and is not liable for such infringement.

332. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,512,983 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not

infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,512,983.

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

**COUNT THIRTY-FOUR**
**Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869**

334. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 333 of the Counterclaims above.

335. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,574,869, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,574,869.

336. The claims of U.S. Patent No. 8,574,869 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

337. U.S. Patent No. 8,574,869 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

338. The alleged invention of U.S. Patent No. 8,574,869 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,574,869 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the

alleged invention of U.S. Patent No. 8,574,869 and would have had a reasonable expectation of success in doing so.

339. The subject matter claimed in U.S. Patent No. 8,574,869 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

340. U.S. Patent No. 8,574,869 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

341. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,574,869 are invalid.

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

**COUNT THIRTY-FIVE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 8,574,869**

343. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 343 of the Counterclaims above.

344. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will

infringe any valid and enforceable claim of U.S. Patent No. 8,574,869 either directly or indirectly, and either literally or under the doctrine of equivalents.

345. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,574,869 either literally or under the doctrine of equivalents and is not liable for such infringement.

346. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,574,869 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,574,869.

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

348. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 8,574,869. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT THIRTY-SIX**
**Declaratory Judgment of Invalidity of U.S. Patent No. 9,441,035**

349. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 349 of the Counterclaims above.

350. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 9,441,035, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 9,441,035.

351. The claims of U.S. Patent No. 9,441,035 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

352. U.S. Patent No. 9,441,035 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

353. The alleged invention of U.S. Patent No. 9,441,035 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 9,441,035 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 9,441,035 and would have had a reasonable expectation of success in doing so.

354. The subject matter claimed in U.S. Patent No. 9,441,035 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

355. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 9,441,035 are invalid.

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

**COUNT THIRTY-SEVEN**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 9,441,035**

357. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 356 of the Counterclaims above.

358. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 9,441,035 either directly or indirectly, and either literally or under the doctrine of equivalents.

359. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,441,035 either literally or under the doctrine of equivalents and is not liable for such infringement.

360. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,441,035 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 9,441,035.

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

362. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 9,441,035. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT THIRTY-EIGHT**
**Declaratory Judgment of Invalidity of U.S. Patent No. 9,714,293**

363. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 362 of the Counterclaims above.

364. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 9,714,293, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 9,714,293.

365. The claims of U.S. Patent No. 9,714,293 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and/or 103.

366. The alleged invention of U.S. Patent No. 9,714,293 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

367. The alleged invention of U.S. Patent No. 9,714,293 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

368. U.S. Patent No. 9,714,293 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

369. The alleged invention of U.S. Patent No. 9,714,293 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 9,714,293 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 9,714,293 and would have had a reasonable expectation of success in doing so.

370. The subject matter claimed in U.S. Patent No. 9,714,293 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

371. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 9,714,293 are invalid.

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

**COUNT THIRTY-NINE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 9,714,293**

373. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 372 of the Counterclaims above.

374. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 9,714,293 either directly or indirectly, and either literally or under the doctrine of equivalents.

375. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,714,293 either literally or under the doctrine of equivalents and is not liable for such infringement.

376. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,714,293 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 9,714,293.

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

**COUNT FORTY**
**Declaratory Judgment of Invalidity of U.S. Patent No. 9,795,672**

378. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 377 of the Counterclaims above.

379. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 9,795,672, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 9,795,672.

380. The claims of U.S. Patent No. 9,795,672 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

381. The alleged invention of U.S. Patent No. 9,795,672 is a natural phenomenon or law in combination with conventional steps. The conventional steps of the alleged invention do not transform the alleged invention as a whole into patent-eligible subject matter.

382. The alleged invention of U.S. Patent No. 9,795,672 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

383. The alleged invention of U.S. Patent No. 9,795,672 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

384. U.S. Patent No. 9,795,672 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

385. The alleged invention of U.S. Patent No. 9,795,672 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 9,795,672 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 9,795,672 and would have had a reasonable expectation of success in doing so.

386. The subject matter claimed in U.S. Patent No. 9,795,672 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

387. U.S. Patent No. 9,795,672 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

388. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 9,795,672 are invalid.

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

**COUNT FORTY-ONE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 9,795,672**

390. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 389 of the Counterclaims above.

391. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 9,795,672 either directly or indirectly, and either literally or under the doctrine of equivalents.

392. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,795,672 either literally or under the doctrine of equivalents and is not liable for such infringement.

393. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,795,672 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 9,795,672.

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

**COUNT FORTY-TWO**
**Declaratory Judgment of Invalidity of U.S. Patent No. 9,884,904**

395. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 394 of the Counterclaims above.

396. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 9,884,904, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 9,884,904.

397. The claims of U.S. Patent No. 9,884,904 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and/or 103.

398. The alleged invention of U.S. Patent No. 9,884,904 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

399. The alleged invention of U.S. Patent No. 9,884,904 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

400. U.S. Patent No. 9,884,904 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

401. The alleged invention of U.S. Patent No. 9,884,904 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 9,884,904 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 9,884,904 and would have had a reasonable expectation of success in doing so.

402. The subject matter claimed in U.S. Patent No. 9,884,904 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

403. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 9,884,904 are invalid.

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

**COUNT FORTY-THREE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 9,884,904**

405. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 404 of the Counterclaims above.

406. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 9,884,904 either directly or indirectly, and either literally or under the doctrine of equivalents.

407. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,884,904 either literally or under the doctrine of equivalents and is not liable for such infringement.

408. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,884,904 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 9,884,904.

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

410. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 9,884,904. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**COUNT FORTY-FOUR**
**Declaratory Judgment of Invalidity of U.S. Patent No. 10,010,611**

411. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 410 of the Counterclaims above.

412. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 10,010,611, based on Genentech's allegation in its Complaint that Pfizer has infringed or will infringe U.S. Patent No. 10,010,611.

413. The claims of U.S. Patent No. 10,010,611 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

414. U.S. Patent No. 10,010,611 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

415. The alleged invention of U.S. Patent No. 10,010,611 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 10,010,611 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 10,010,611 and would have had a reasonable expectation of success in doing so.

416. The subject matter claimed in U.S. Patent No. 10,010,611 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

417. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 10,010,611 are invalid.

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

**COUNT FORTY-FIVE**
**Declaratory Judgment of Non-infringement of U.S. Patent No. 10,010,611**

419. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 418 of the Counterclaims above.

420. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 10,010,611 either directly or indirectly, and either literally or under the doctrine of equivalents.

421. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 10,010,611 either literally or under the doctrine of equivalents and is not liable for such infringement.

422. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 10,010,611 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 10,010,611.

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

424. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 10,010,611.

Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

**PRAYER FOR RELIEF**

Wherefore, Pfizer prays that this Court enter judgment in its favor and against Plaintiffs as follows:

A. Adjudging and decreeing that Plaintiffs be denied all relief requested under the their Complaint;

B. Declaring that Pfizer has not and will not infringe any valid and enforceable claim of any asserted patent;

C. Declaring that the patents described in Paragraphs 38 to 59 of Pfizer's Counterclaims are invalid;

D. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Pfizer or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Pfizer, or charging them either orally or in writing with infringement of any patent asserted herein against Pfizer;

E. Granting Pfizer Judgment in its favor on Plaintiffs' Complaint;

F. Denying Plaintiffs' request for injunctive relief;

G. Denying Plaintiffs' request for any monetary damages;

H. Finding that Plaintiffs did not have a good-faith basis for bringing this action;

I. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Pfizer its costs and reasonable attorneys' fees;

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

K. An award of taxable costs;

L. An award of interest; and

M. Awarding any other such relief as is just and proper.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

*/s/ Dominick T. Gattuso*
Dominick T. Gattuso (No. 3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
Telephone: (308) 472-7300
Email: dgattuso@hegh.law

*Attorneys for Pfizer, Inc.*

OF COUNSEL:

WILLKIE FARR & GALLAGHER LLP
Thomas J. Meloro
Michael W. Johnson
Dan Constantinescu
787 Seventh Avenue
New York, NY 10019
(212) 728-8000

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