UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

AMGEN INC.'S ANSWER TO DEFENDANTS' COUNTERCLAIMS

In response to Defendants' March 30, 2007 First Amended Answer and Counterclaims to Plaintiff's Complaint herein, and the Court's March 30, 2007 Order granting Amgen Inc.'s ("Amgen") Motion to Dismiss Counterclaim II and Affirmative Defense XII, Amgen answers as follows:

1. Amgen admits that Defendants are seeking relief based on the assertions set forth in their Counterclaims. Amgen denies Defendants' Counterclaims have any merit and specifically denies the allegations contained in paragraph 1 of Defendants' Counterclaims.

2. Amgen admits that Ortho Biotech Products, L.P. ("Ortho") sells Procrit® under a license from Amgen and that Procrit® contains the same active ingredient as EPOGEN®. Amgen's license with Ortho speaks for itself, and Amgen denies Defendants' characterization of

it. Amgen denies the remaining allegations contained in paragraph 2 of Defendants' Counterclaims.

3. Amgen denies the allegations contained in paragraph 3 of Defendants' Counterclaims.

4. Amgen admits that Defendants are seeking relief based on the assertions set forth in their Counterclaims. Amgen denies the allegations contained in paragraph 4 of Defendants' Counterclaims.

THE PARTIES

5. On information and belief, Amgen admits the allegations in paragraph 5 of Defendants' Counterclaims.

6. On information and belief, Amgen admits the allegations in paragraph 6 of Defendants' Counterclaims.

7. On information and belief, Amgen admits the allegations in paragraph 7 of Defendants' Counterclaims.

8. The statements in paragraph 8 are neither averments nor allegations to which a response is required, and Amgen otherwise denies these allegations.

9. Admitted.

JURISDICTION AND VENUE

10. Admitted.

11. Admitted.

12. Admitted.

FACTUAL ALLEGATIONS

13. Admitted.

14. Amgen admits that Defendants have defined "ESAs" so that such products may be used to treat anemia patients by promoting the production of red blood cells. Amgen further admits that anemia is a condition that is marked, in part, by having less than normal numbers of circulating red blood cells. Amgen denies the remaining allegations contained in paragraph 14 of Defendants' Counterclaims.

15. Amgen admits that under the definition of ESAs in Defendants' counterclaim, doctors use ESAs to treat anemia for a variety of indications, including ESRD, CKD, and oncology.

16. The allegations in paragraph 16 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

17. Amgen admits that there are approximately 400,000 ESRD patients in the United States and that many of those patients regularly receive treatment at dialysis centers to filter their blood through hemodialysis machines. Amgen further admits that dialysis patients typically suffer from anemia and require treatment to achieve normal or near-normal hemoglobin levels. Amgen denies the remaining allegations contained in paragraph 17 of Defendants' Counterclaims.

18. Amgen admits that any party seeking to market a drug for the treatment of anemia in the U.S. must obtain FDA approval. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 18 of Defendants' Counterclaims, and on that basis denies such allegations.

19. The allegations in paragraph 19 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

20. Amgen admits that EPOGEN® was introduced into the U.S. marketplace in 1989 and that healthcare providers use EPOGEN® to treat anemia. Amgen further admits that it sold more than $2.4 billion worth of EPOGEN® worldwide in 2005. Amgen denies all remaining allegations of paragraph 20 of Defendants' Counterclaims.

21. Amgen admits that ARANESP® was introduced into the United States marketplace in 2001 and that healthcare providers use ARANESP® to treat anemia. Amgen further admits that it sold more than $ 2.1 billion worth of ARANESP® worldwide in 2005. Amgen denies all remaining allegations of paragraph 21 of Defendants' Counterclaims.

22. Amgen admits that EPOGEN® and ARANESP® have been approved by the FDA to treat anemia associated with ESRD. Amgen also admits that both products are sold in the United States. Amgen further admits that Ortho sells Procrit® under a license from Amgen and that Procrit® contains the same active ingredient as EPOGEN®. Amgen's license with Ortho speaks for itself, and Amgen denies Defendants' characterization of it. Amgen denies all remaining allegations of paragraph 22 of Defendants' Counterclaims.

23. The allegations in paragraph 23 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

24. Amgen admits that large dialysis organizations ("LDOs") treat patients with ESRD and Amgen contracts with LDOs to sell them EPOGEN® and ARANESP®. Amgen denies the remaining allegations contained in paragraph 24 of Defendants' Counterclaims.

25. Amgen admits that in addition to LDOs, small and medium chain dialysis centers, independent dialysis centers and some hospitals also treat ESRD patients. Amgen denies the remaining allegations contained in paragraph 25 of Defendants' Counterclaims.

26. Amgen denies the allegations contained in paragraph 26 of Defendants' Counterclaims.

27. Amgen admits that it holds patents that Roche's pegylated recombinant human erythropoietin ("peg-EPO") violates and that Amgen is rightfully protecting its patents by seeking to stop Roche's infringement. Amgen also admits that Roche must obtain FDA approval of peg-EPO before it can market it in the U.S. Amgen further admits that it has lawful and appropriate agreements and relationships with dialysis centers. Finally, Amgen admits that healthcare providers will analyze, among other things, the safety, efficacy, and operational aspects of any drug the provider uses to treat anemic ESRD patients. Amgen denies the remaining allegations contained in paragraph 27 of Defendants' Counterclaims.

28. Amgen denies the allegations contained in paragraph 28 of Defendants' Counterclaims.

29. The allegations in paragraph 29 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

30. Amgen admits that CKD patients suffer from some level of reduced kidney function. Those CKD patients who are not ESRD patients generally do not receive dialysis treatment. Amgen denies all remaining allegations of paragraph 30 of Defendants' Counterclaims.

31. Amgen admits that some CKD patients suffer anemia. Amgen further admits that any party seeking to market a drug for the treatment of anemia in the U.S. must obtain FDA approval. Amgen denies the remaining allegations contained in paragraph 31 of Defendants' Counterclaims.

32. The allegations in paragraph 32 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

33. Amgen admits that the FDA has approved the use of EPOGEN® and ARANESP® to treat anemia associated with CKD. Amgen admits that Ortho sells Procrit® under a license from Amgen, that Procrit® contains the same active ingredient as EPOGEN®, and that medical providers use Procrit® to treat anemia in CKD patients. Amgen's license with Ortho speaks for itself, and Amgen denies Defendants' characterization of it. Amgen denies all remaining allegations of paragraph 33 of Defendants' Counterclaims.

34. Amgen admits that Procrit® and ARANESP® are administered at, among other locations, doctor's offices, hospitals and patient homes, and that medical providers or patients may obtain Procrit® or ARANESP® through, among others, specialty distributors, hospitals, general purchasing organizations, and retail pharmacies. Amgen denies all remaining allegations of paragraph 34 of Defendants' Counterclaims.

35. Amgen admits that ARANESP® was introduced into the United States marketplace in 2001. Amgen denies all remaining allegations of paragraph 35 of Defendants' Counterclaims.

36. Amgen admits that the United States Patent and Trademark Office has issued patents assigned to it regarding erythropoietin and processes related to erythropoietin. Amgen

also admits that courts have previously found that companies illegally violated Amgen's patents. Amgen further admits that any party, including Roche, seeking to market a drug for the treatment of anemia in the U.S., must first obtain FDA approval. Amgen finally admits that healthcare providers will analyze, among other things, the safety, efficacy and operational aspects of any drugs the provider uses to treat anemia in CKD patients. Amgen denies all remaining allegations of paragraph 36 of Defendants' Counterclaims.

37. Amgen denies the allegations contained in paragraph 37 of Defendants' Counterclaims.

38. On information and belief, Amgen admits that Defendants are seeking FDA approval to market and sell peg-EPO in the United States. On information and belief, Amgen denies that: (1) Defendants' peg-EPO is a "unique anemia medication" or (2) Defendants' peg-EPO product provides better patient outcomes than EPOGEN® or ARANESP®. Amgen further denies that peg-EPO is a "major threat." Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 38 of Defendants' Counterclaims and on that basis denies such allegations.

39. On information and belief, Defendants' peg-EPO product contains the same chemical entity as recombinant human erythropoietin and, like recombinant human erythropoietin, acts to increase the production of reticulocytes and red blood cells. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 39 of Defendants' Counterclaims and on that basis denies such allegations.

40. On information and belief, Amgen denies that Defendants' peg-EPO materially differs from EPOGEN® or that peg-EPO offers physicians and patients either more appropriate medical treatment or provides improved convenience or compliance than EPOGEN®. Amgen

lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 40 of Defendants' Counterclaims and on that basis denies such allegations.

41. Amgen denies the allegations contained in paragraph 41 of Defendants' Counterclaims.

42. On information and belief, Amgen admits that Roche's peg-EPO product is being reviewed by the FDA. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 42 of Defendants' Counterclaims and on that basis denies such allegations.

43. Amgen admits that on information and belief it had asserted that the FDA would act on Defendants' regulatory application in February 2007 but that has not occurred. Defendants' actions indicate they expected to receive approval from FDA imminently. Amgen denies the remaining allegations of paragraph 43 of Defendants' Counterclaims and on that basis denies such allegations.

44. Amgen denies the allegations contained in paragraph 44 of Defendants' Counterclaims.

45. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 45 of Defendants' Counterclaims.

46. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 46 of Defendants' Counterclaims.

47. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that it provided briefing to the ITC Commission in 2006, but denies the remaining allegations contained in paragraph 47 of Defendants' Counterclaims.

48. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that ITC Investigation No. 337-TA-568 was terminated. Amgen denies the remaining allegations contained in paragraph 48 of Defendants' Counterclaims.

49. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen states that the cited statute speaks for itself, and denies the remaining allegations contained in paragraph 49 of Defendants' Counterclaims.

50. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 50 of Defendants' Counterclaims.

51. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 51 of Defendants' Counterclaims.

52. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that Roche filed for summary determination on May 19, 2006, but denies the remaining allegations contained in paragraph 52 of Defendants' Counterclaims.

53. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that it filed for Objections and Responses to Respondents' First Set of Interrogatories dated May 30, 2006, but denies the remaining allegations contained in paragraph 53 of Defendants' Counterclaims.

54. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 54 of Defendants' Counterclaims.

55. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 55 of Defendants' Counterclaims.

56. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that on August 31, 2006, the ITC Commission terminated the investigation, Amgen states that the Commission's decision speaks for itself, and Amgen denies the remaining allegations contained in paragraph 56 of Defendants' Counterclaims.

57. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies Defendants' Counterclaims have any merit and specifically denies the allegations contained in paragraph 57 of Defendants' Counterclaims.

58. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is

required, Amgen denies Defendants' counterclaims have any merit and specifically denies the allegations contained in paragraph 58 of Defendants' Counterclaims.

59. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that it served third party subpoenas on Dialysis Purchasing Alliance, Fresenius Medical Care, Gambro Inc., and DaVita Inc. during the course of discovery in the ITC case, but denies the remaining allegations contained in paragraph 59 of Defendants' Counterclaims.

60. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that conducted depositions of Roche employees during the course of discovery in the ITC case, but denies the remaining allegations contained in paragraph 60 of Defendants' Counterclaims.

61. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 61 of Defendants' Counterclaims.

62. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that it has asserted claims 3, 4, and 6 of U.S. Patent No. 5,621,080 against Roche, but denies the remaining allegations contained in paragraph 62 of Defendants' Counterclaims.

63. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is

required, Amgen states that the Federal Circuit's prior decisions speak for themselves, and denies the remaining allegations contained in paragraph 63 of Defendants' Counterclaims.

64. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that it has asserted that Roche infringes the '080 Patent in this case, but denies remaining allegations contained in paragraph 64 of Defendants' Counterclaims.

65. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen admits that it has asserted claim 9 of the '933 Patent against Roche in the current lawsuit, Amgen states that the prior decisions by the district court and the Federal Circuit speak for themselves, and Amgen denies the remaining allegations contained in paragraph 65 of Defendants' Counterclaims.

66. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen lacks knowledge or information sufficient to form a belief as to Roche's expectation, and Amgen denies the remaining allegations contained in paragraph 66 of Defendants' Counterclaims.

67. On March 30, 2007, this Court dismissed Defendants' claims as to "sham litigation." Thus, these allegations are inappropriate and irrelevant. To the extent a response is required, Amgen denies the allegations contained in paragraph 67 of Defendants' Counterclaims.

68. Amgen denies that Defendants have alleged with sufficient particularity the allegations of fraud and inequitable conduct set forth at paragraphs 38-45 of Defendants' Answer

and denies the substance of the allegations set forth at paragraphs 38-45 of Defendants' Answer. Amgen further denies the remaining allegations of paragraph 68 of Defendants' Counterclaims.

69. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 69 of Defendants' Counterclaims and on that basis denies such allegations.

70. Amgen denies the allegations contained in paragraph 70 of Defendants' Counterclaims.

71. Amgen denies the allegations contained in paragraph 71 of Defendants' Counterclaims.

72. Amgen denies the allegations contained in paragraph 72 of Defendants' Counterclaims.

73. Amgen denies the allegations contained in paragraph 73 of Defendants' Counterclaims.

74. Amgen denies the allegations contained in paragraph 74 of Defendants' Counterclaims.

75. Amgen denies the allegations contained in paragraph 75 of Defendants' Counterclaims.

76. Amgen denies the allegations contained in paragraph 76 of Defendants' Counterclaims.

77. Amgen denies the allegations contained in paragraph 77 of Defendants' Counterclaims.

78. Amgen denies the allegations contained in paragraph 78 of Defendants' Counterclaims.

79. Amgen denies the allegations contained in paragraph 79 of Defendants' Counterclaims.

80. Amgen denies the allegations contained in paragraph 80 of Defendants' Counterclaims.

81. Amgen denies the allegations contained in paragraph 81 of Defendants' Counterclaims.

82. Amgen denies the allegations contained in paragraph 82 of Defendants' Counterclaims.

COUNT I

(Monopolization And Attempted Monopolization (15 U.S.C. §2))
(Walker Process Antitrust Claim – ESRD ESA and CKD ESA Markets)

83. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-82 of this Answer, as if fully set forth herein.

84. Amgen denies that Defendants have alleged with sufficient particularity the allegations of fraud and inequitable conduct set forth at paragraphs 38-53 of Defendants' Answer and denies the substance of the allegations set forth at paragraphs 38-53 of Defendants' Answer. Amgen further denies the remaining allegations of paragraph 84 of Defendants' Counterclaims.

85. Amgen denies that Defendants have alleged with sufficient particularity the allegations of fraud and inequitable conduct set forth at paragraphs 38-53 of Defendants' Answer and denies the substance of the allegations set forth at paragraphs 38-53 of Defendants' Answer. Amgen further denies the remaining allegations of paragraph 85 of Defendants' Counterclaims.

86. Amgen admits that it commenced the present action for declaratory judgment of infringement of the patents-in-suit against Roche, but denies the remaining allegations of paragraph 86 of Defendants' Counterclaims.

87. Amgen denies the allegations contained in paragraph 87 of Defendants' Counterclaims.

88. Amgen denies the allegations contained in paragraph 88 of Defendants' Counterclaims.

89. Amgen denies the allegations contained in paragraph 89 of Defendants' Counterclaims.

90. Amgen denies the allegations contained in paragraph 90 of Defendants' Counterclaims.

91. Amgen denies the allegations contained in paragraph 91 of Defendants' Counterclaims.

COUNT II

OMITTED

92. Omitted

93. Omitted

94. Omitted

95. Omitted

96. Omitted

97. Omitted

98. Omitted

COUNT III

(Monopolization of ESRD ESA Market (15 U.S.C. §2)

99. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-98 of this Answer, as if fully set forth herein.

100. Amgen denies the allegations contained in paragraph 100 of Defendants' Counterclaims.

101. Amgen denies the allegations contained in paragraph 101 of Defendants' Counterclaims.

102. Amgen denies the allegations contained in paragraph 102 of Defendants' Counterclaims.

103. Amgen denies the allegations contained in paragraph 103 of Defendants' Counterclaims.

COUNT IV

(Attempted Monopolization of CKD ESA Market 15 U.S.C. §2)

104. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-103 of this Answer, as if fully set forth herein.

105. Amgen denies the allegations contained in paragraph 105 of Defendants' Counterclaims.

106. Amgen denies the allegations contained in paragraph 106 of Defendants' Counterclaims.

107. Amgen denies the allegations contained in paragraph 107 of Defendants' Counterclaims.

108. Amgen denies the allegations contained in paragraph 108 of Defendants' Counterclaims.

COUNT V

(Unreasonable Restraints of Trade in the ESRD ESA and CKD ESA Markets (15 U.S.C. §1)

109. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-108 of this Answer, as if fully set forth herein.

110. Amgen admits that it has entered into contracts with third parties that affect interstate commerce, and denies the remaining allegations contained in paragraph 110 of Defendants' Counterclaims.

111. Amgen denies the allegations contained in paragraph 111 of Defendants' Counterclaims.

112. Amgen denies the allegations contained in paragraph 112 of Defendants' Counterclaims.

113. Amgen denies the allegations contained in paragraph 113 of Defendants' Counterclaims.

COUNT VI

(Tortious Interference With Prospective Business Relationships)

114. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-113 of this Answer, as if fully set forth herein.

115. Amgen lacks knowledge or information sufficient to form a belief as to the truth of paragraph 115 of Defendants' Counterclaims, and on that basis denies such allegations.

116. Amgen denies the allegations contained in paragraph 116 of the Defendants' Counterclaims.

117. Amgen denies the allegations contained in paragraph 117 of the Defendants' Counterclaims.

118. Amgen denies the allegations contained in paragraph 118 of the Defendants' Counterclaims.

119. Amgen denies the allegations contained in paragraph 119 of the Defendants' Counterclaims.

120. Amgen denies the allegations contained in paragraph 120 of the Defendants' Counterclaims.

COUNT VII

(Discouraging Competition in Violation of California's Cartwright Act)

121. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-120 of this Answer, as if fully set forth herein.

122. Amgen denies the allegations contained in paragraph 122 of the Defendants' Counterclaims.

123. Amgen denies the allegations contained in paragraph 123 of the Defendants' Counterclaims.

COUNT VIII

(Discouraging Competition in Violation of the New Jersey Antitrust Act)

124. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-123 of this Answer, as if fully set forth herein.

125. Amgen denies the allegations contained in paragraph 125 of the Defendants' Counterclaims.

126. Amgen denies the allegations contained in paragraph 126 of the Defendants' Counterclaims.

COUNT IX

(Unfair and Deceptive Business Practices in Violation of the Massachusetts Consumer and Business Protection Act, Mass. Gen. Laws c. 93A)

127. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-126 of this Answer, as if fully set forth herein.

128. The allegations in paragraph 128 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

129. The allegations in paragraph 129 of Defendants' Counterclaims call for a legal conclusion, and no response is required. To the extent any allegation is intended to be contained within this paragraph, Amgen denies the allegation.

130. Amgen denies the allegations contained in paragraph 130 of the Defendants' Counterclaims.

131. Amgen denies the allegations contained in paragraph 131 of the Defendants' Counterclaims.

132. Amgen denies the allegations contained in paragraph 132 of the Defendants' Counterclaims.

COUNT X

(Declaratory Judgment of Patent Invalidity)

133. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-132 of this Answer, as if fully set forth herein.

134. Amgen admits that the U.S. PTO issued the '868, '933, '698, '080, '349, and '422 Patents on August 15, 1995, August 20, 1996, April 8, 1997, April 15, 1997, May 26, 1998, and September 21, 1999, respectively. Amgen admits that Fu-Kuen Lin was the sole inventor of the inventions claimed in each of those patents. Amgen denies the remaining allegations contained in paragraph 134 of the Defendant's Counterclaims.

135. Amgen admits that Roche alleges that there is an actual and justiciable controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 with respect to the validity of the '868, '933, '698, '080, '349, and '422 Patents.

136. Amgen denies the allegations contained in paragraph 136 of Defendants' Counterclaims.

COUNT XI

(Declaratory Judgment of Non-Infringement)

137. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-136 of this Answer, as if fully set forth herein.

138. Admitted.

139. Amgen denies that Defendants' counterclaims and their § 271(e)(1) affirmative defense have any merit and specifically denies the allegations contained in paragraph 139 of the Defendant's Counterclaims.

COUNT XII

(Declaratory Judgment of Unenforceability)

140. Amgen incorporates its responses to and denials of the allegations contained in paragraphs 1-139 of this Answer, as if fully set forth herein.

141. Amgen admits that Roche alleges that there is an actual and justiciable controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 with respect to the enforceability of the '868, '933, '698, '080, '349, and '422 Patents.

142. Amgen denies the allegations contained in paragraph 142 of the Defendant's Counterclaims.

143. Amgen denies the allegations contained in paragraph 143 of Defendants' Counterclaims.

144. Amgen denies the allegations contained in paragraph 144 of Defendants' Counterclaims.

AMGEN'S AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE – FAILURE TO STATE A CLAIM

145. The allegations in Defendants' Counterclaims fail to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE –EQUITABLE ESTOPPEL RE VALIDITY OF AMGEN'S PATENTS

146. Defendants are equitably estopped from seeking declaratory judgment of invalidity based on the Roche Global Agreement. This Agreement is a communication between Amgen and Defendants regarding the validity of Amgen's patents, including the patents at issue in this litigation.

147. In this agreement, Defendants acknowledged the validity of Amgen's patents. Amgen relied upon this acknowledgement in consideration for its decision to settle the parties' then-pending dispute regarding, *inter alia*, Defendants epoetin-beta product – the same product used to manufacture Defendants' peg-EPO product.

148. Amgen is prejudiced by Defendants' failure to adhere to the terms of the Agreement and their challenge to the validity of Amgen's patents in this action.

149. Defendants' claim for declaratory judgment of invalidity is barred by equitable estoppel.

THIRD AFFIRMATIVE DEFENSE -
EQUITABLE ESTOPPEL RE ENFORCEABILITY OF AMGEN'S PATENTS

150. Defendants are equitably estopped from seeking declaratory judgment of invalidity based on the Roche Global Agreement. This Agreement is a communication between Amgen and Defendants regarding the infringement of Amgen's patents, including the patents at issue in this litigation.

151. In this agreement, Defendants acknowledged the infringement of Amgen's patents. Amgen relied upon this acknowledgement in consideration for its decision to settle the parties' then-pending dispute regarding, *inter alia,* Defendants epoetin-beta product – the same product used to manufacture Defendants' peg-EPO product.

152. Amgen is prejudiced by Defendants' failure to adhere to the terms of the Agreement and their challenge of infringement of Amgen's patents in this action.

153. Defendants' claim for declaratory judgment of non-infringement is barred by equitable estoppel.

FOURTH AFFIRMATIVE DEFENSE –AMGEN'S CONDUCT WAS LAWFUL

154. To the extent that Amgen engaged in any of the conduct alleged in the Counterclaims, its conduct was reasonable, justified, excused, privileged and/or in pursuit of lawful and legitimate business interests.

FIFTH AFFIRMATIVE DEFENSE – AMGEN'S CONDUCT WAS PROCOMPETITIVE

155. The Counterclaims are barred on the ground that the alleged conduct was, either in whole or in part, procompetitive in nature, and will promote, encourage, and increase competition. Accordingly, Amgen's conduct was reasonable, justified, and privileged.

SIXTH AFFIRMATIVE DEFENSE –
DEFENDANTS' FAIL TO IDENTIFY ANY COGNIZABLE ANTITRUST INJURIES

156. The injuries and damages alleged by Defendants do not constitute legally cognizable antitrust injuries.

SEVENTH AFFIRMATIVE DEFENSE –
DEFENDANTS' ALLEGED INJURIES WERE NOT CAUSED BY AMGEN

157. The damages allegedly suffered by Defendants were not caused in fact by any conduct or act of Amgen.

EIGHTH AFFIRMATIVE DEFENSE –
DEFENDANTS' ALLEGED INJURIES WERE NOT PROXIMATELY CAUSED BY AMGEN

158. The damages allegedly suffered by Defendants were not proximately caused by any conduct or act of Amgen.

NINTH AFFIRMATIVE DEFENSE – UNCLEAN HANDS

159. Defendants' claims are barred by the doctrine of unclean hands.

TENTH AFFIRMATIVE DEFENSE –
DEFENDANTS' FAILURE TO MITIGATE ALLEGED DAMAGES

160. Defendants have failed to exercise reasonable care and diligence to mitigate their alleged injuries and damages, if any.

ELEVENTH AFFIRMATIVE DEFENSE –
DEFENDANTS' SELF-INFLICTED LOSSES

161. Any loss or damage allegedly suffered by Defendants was proximately caused by Defendants' decisions and business judgments in connection with the matters alleged in the Counterclaims and not by Amgen's alleged conduct or actions.

TWELFTH AFFIRMATIVE DEFENSE - DEFENDANTS' 93A CLAIM IS IMPROVIDENTLY PLED

162. Defendants' Chapter 93A claim is barred because the conduct at issue did not occur primarily and substantially within the Commonwealth.

THIRTEENTH AFFIRMATIVE DEFENSE – DEFENDANTS' DAMAGES ARE SPECULATIVE

163. Defendants' alleged damages, if any, are speculative and impossible to ascertain.

FOURTEENTH AFFIRMATIVE DEFENSE – NO IRREPARABLE HARM OR INJURY

164. There is no irreparable harm or injury to Defendants, and therefore they are not entitled to any injunctive relief.

FIFTEENTH AFFIRMATIVE DEFENSE – NO STANDING

165. Defendants' Counterclaims are barred because Defendants lack standing.

SIXTEENTH AFFIRMATIVE DEFENSE – LACHES

166. Defendants' Counterclaims are barred by the doctrine of laches.

SEVENTEENTH AFFIRMATIVE DEFENSE – WAIVER

167. Defendants' Counterclaims are barred by the doctrine of waiver.

EIGHTEENTH AFFIRMATIVE DEFENSE – ESTOPPEL

168. Defendants' Counterclaims are barred by the doctrine of estoppel.

OTHER AFFIRMATIVE DEFENSES

169. Amgen hereby gives notice that it intends to rely upon any other defense that may become available in this case and hereby reserves the right to amend this Answer to assert any such defense.

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

April 16, 2007

/s/ Michael R. Gottfried

D. Dennis Allegretti (BBO# 545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (617) 289-9200
Facsimile: (617) 289-9201

Of Counsel:
Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

Lloyd R. Day, Jr. (*pro hac vice*)
DAY CASEBEER MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

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/s/ Michael R. Gottfried
Michael R. Gottfried

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