

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)
 AMGEN INC.,)
)
 Plaintiff,)
)
 v.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 and HOFFMANN-LA ROCHE INC.,)
)
 Defendants.)
 _____)

CIVIL ACTION No.: 05-CV-12237WGY

**DECLARATION OF KRISTA M. RYCROFT IN SUPPORT OF
ROCHE’S OPPOSITION TO AMGEN INC.’S MOTION
FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT**

I, Krista M. Rycroft, hereby declare under penalty of perjury that:

1. I am an attorney admitted to the Bar of the State of New York and am an associate in the law firm of Kaye Scholer LLP, counsel for Defendants in the above captioned case.

2. I make this declaration in support of Roche’s Opposition to Amgen Inc.’s Motion for Summary Judgment of No Inequitable Conduct, the accompanying Rule 56.1 Statement Of Undisputed Material Facts and the Supporting Declarations of Michael Sofocleous, Carolyn Bertozzi, Ph.D and Charles G. Zaroulis, Ph.D.

3. Exhibit 1 is a true and correct copy of the Egrie Input File. (AM-ITC 01072474-501).

4. Exhibit 2 is a true and correct copy of U.S. Patent No. 5,441,868.

5. Exhibit 3 is a true and correct copy of a Protest by Dr. Lai in the '178 File History (Paper 31), dated July 23, 1993. (AM-ITC 00941255-61 (attachments excluded)).

6. Exhibit 4 is a true and correct copy of an Office Action in the '178 File History (Paper 34), mailed on December 29, 1993. (AM-ITC 00941410-15).

7. Exhibit 5 is a true and correct copy of U.S. Patent No. 5,547,933.

8. Exhibit 6 is a true and correct copy of Miyake *et al.*, "Purification of Human Erythropoietin," *J. Biol. Chem.*, Vol. 252, No. 15, pp. 5558-64 (Aug. 1977). (AM-ITC 00987639-49).

9. Exhibit 7 is a true and correct copy of portions of the Rebuttal Expert Report of Stephen Kunin, dated May 11, 2007.

10. Exhibit 8 is a true and correct copy of a Declaration of Michael Borun Accompanying a Petition to Make Special in the '179 File History (Paper 3), dated February 9, 1988. (AM-ITC 00953134-41).

11. Exhibit 9 is a true and correct copy of a Preliminary Amendment in the '179 File History (Paper 7), dated October 23, 1987. (AM-ITC 00953195-203).

12. Exhibit 10 is a true and correct copy of Applicant's Second Preliminary Amendment in the '179 File History (Paper 8), dated May 24, 1988. (AM-ITC 00953204-25).

13. Exhibit 11 is a true and correct copy of an Examiner Interview Summary Record in the '179 File History (Paper 30) dated November 13, 1993. (AM-ITC 00953602-03).

14. Exhibit 12 is a true and correct copy of Applicant's Amendment and Remarks Under 37 C.F.R. §§ 1.111 and 1.115 in the '179 File History (Paper 33), dated January 3, 1994. (AM-ITC 00953636-48).

15. Exhibit 13 is a true and correct copy of an undated Information Disclosure Statement in the '179 File History (Paper 44). (AM-ITC 00953710-11).
16. Exhibit 14 is a true and correct copy of a Preliminary Amendment in the '381 File History (Paper 4), dated June 6, 1995. (AM-ITC 00898298-301).
17. Exhibit 15 is a true and correct copy of an IDS filed in the '381 File History (Paper 6), dated January 3, 1996. (AM-ITC 00898307-33).
18. Exhibit 16 is a true and correct copy of an Interview Summary in the '381 File History (Paper 7), dated December 11, 1996. (AM-ITC 00898334-37).
19. Exhibit 17 is a true and correct copy of a Preliminary Amendment in the '369 File History (Paper 5), dated June 6, 1995. (AM-ITC 00898621-24).
20. Exhibit 18 is a true and correct copy of a Second Preliminary Amendment in the '369 File History (Paper 8), dated December 20, 1996. (AM-ITC 00898654-63).
21. Exhibit 19 is a true and correct copy of an Information Disclosure Statement and accompanying PTO-1449 in the '369 File History (Paper 6), dated January 3, 1996. (AM-ITC 00898625-51).
22. Exhibit 20 is a true and correct copy of an Information Disclosure Statement in the '369 File History (Paper 9), dated December 20, 1996. (AM-ITC 00898691-92).
23. Exhibit 21 is a true and correct copy of an Associate Power of Attorney in the '073 File History (Paper 11), dated December 30, 1992. (AM-ITC 00899119-21).
24. Exhibit 22 is a true and correct copy of an Examiner Interview Summary Record in the '369 File History (Paper 7), dated December 11, 1996. (AM-ITC 00898652-53).
25. Exhibit 23 is a true and correct copy of a Preliminary Amendment in the '178 File History (Paper 3), dated October 23, 1987. (AM-ITC 00941081-88).

26. Exhibit 24 is a true and correct copy of Applicant's Amendment and Request for Reconsideration Under 37 C.F.R. §§ 1.111 and 1.115 in the '874 File History (Paper 42), dated February 16, 1995. (AM-ITC 00941507-21).

27. Exhibit 25 is a true and correct copy of a communication from Examiner Schain to Mr. Borun in the '178 File History (Paper 21). (AM-ITC 00941224-27).

28. Exhibit 26 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 32), dated November 18, 1993. (AM-ITC 00941406-07).

29. Exhibit 27 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 33), dated November 22, 1993. (AM-ITC 00941408-409).

30. Exhibit 28 is a true and correct copy of a Notice of Change of Address in the '178 File History (Paper 30). (AM-ITC 00941253-54).

31. Exhibit 29 is a true and correct copy of a Third Preliminary Amendment and Terminal Disclaimer Pursuant to 37 C.F.R. §1.321 in the '556 File History (Paper 6), dated December 20, 1996. (AM-ITC 00868077-88).

32. Exhibit 30 is a true and correct copy of an Interview Summary from the '556 File History (Paper 4), dated December 11, 1996. (AM-ITC 00868071-73).

33. Exhibit 31 is a true and correct copy of an Information Disclosure Statement and accompanying PTO-1449 in the '556 File History (Paper 7), dated December 20, 1996. (AM-ITC 00868126-55).

34. Exhibit 32 is a true and correct copy of the Brief for the Senior Party Lin in the '334 Interference. (AM-ITC 00832862-943).

35. Exhibit 33 is a true and correct copy of a June 28, 1994 letter from John Brown to the European Patent Office. (AM-ITC 00312754).

36. Exhibit 34 is a true and correct copy of portions of the April 2, 2007 deposition transcript of Steven Odre.

37. Exhibit 35 is a true and correct copy of portions of the February 14, 2000 deposition transcript of Steven Odre.

38. Exhibit 36 is a true and correct copy of an Associate Power of Attorney in the '179 File History (Paper 2), dated February 9, 1988. (AM-ITC 00953131-33).

39. Exhibit 37 is a true and correct copy an Examiner Interview Summary Record in the '179 File History (Paper 10) dated September 14, 1988. (AM-ITC 00953232-34).

40. Exhibit 38 is a true and correct copy of Applicant's Reply Under 37 C.F.R. § 1.111 in the '179 File History (Paper 14), dated September 27, 1988. (AM-ITC 00953272-78).

41. Exhibit 39 is a true and correct copy of a Petition for Access filed in the '179 File History (Paper 12), dated September 27, 1988. (AM-ITC 00953250-56).

42. Exhibit 40 is a true and correct copy of a Request for Withdrawal of Suspension in the '179 File History (Paper 20), dated May 1, 1989. (AM-ITC 00953313-17).

43. Exhibit 41 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (attached to Paper 4), dated July 20, 1988. (AM-ITC 00941101).

44. Exhibit 42 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 8) dated January 26, 1989. (AM-ITC 00941145-46).

45. Exhibit 43 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 14) dated June 22, 1989. (AM-ITC 00941184-85).

46. Exhibit 44 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 17), dated December 20, 1989. (AM-ITC 00941204-05).

47. Exhibit 45 is a true and correct copy of a Power of Attorney in the '178 File History (Paper 24), dated February 22, 1990. (AM-ITC 00941241-42).
48. Exhibit 46 is a true and correct copy of portions of the March 29, 2007 deposition transcript of Stuart Watt.
49. Exhibit 47 is a true and correct copy of portions of the September 7, 2000 trial testimony of Stuart Watt.
50. Exhibit 48 is a true and correct copy of a Second Preliminary Amendment and Terminal Disclaimer Pursuant to 37 C.F.R. § 1.321 in the '381 File History (Paper 9), dated December 20, 1996. (AM-ITC 00898342-53).
51. Exhibit 49 is a true and correct copy of an Examiner Interview Summary Record in the '369 File History (Paper 11), dated May 6, 1997. (AM-ITC 00898727-28).
52. Exhibit 50 is a true and correct copy of an Examiner Interview Summary Record in the '197 File History (Paper 24), dated March 1, 1995. (AM-ITC 00899176-77).
53. Exhibit 51 is a true and correct copy of an Examiner Interview Summary Record in the '197 File History (Paper 32), dated April 21, 1999. (AM-ITC 00899440-41).
54. Exhibit 52 is a true and correct copy of a Terminal Disclaimer in the '197 File History (Paper 35), dated April 26, 1999. (AM-ITC 00899686-88).
55. Exhibit 53 is a true and correct copy of an Examiner Interview Summary Record in the '774 File History (Paper 46), dated October 18, 1995. (AM-ITC 00941538-39).
56. Exhibit 54 is a true and correct copy of portions of a November 9, 1999 deposition transcript of Joan Egrie.
57. Exhibit 55 is a true and correct copy of portions of the November 10, 1999 deposition transcript of Joan Egrie.

58. Exhibit 56 is a true and correct copy of a Declaration of Fu-Kuen Lin, submitted in Interference No. 102,334, dated March 18, 1991. (AM-ITC 00295809-16).

59. Exhibit 57 is a true and correct copy of portions of the March 27, 2007 deposition transcript of Joan Egrie.

60. Exhibit 58 is a true and correct copy of portions of the March 28, 2007 deposition transcript of Dr. Lin.

61. Exhibit 59 is a true and correct copy of portions of the March 9, 2007 deposition transcript of Thomas Strickland.

62. Exhibit 60 is a true and correct copy of the Declaration of Thomas Strickland Pursuant to 37 C.F.R. §1.132, dated November 30, 1988. (AM-ITC 00941119-44).

63. Exhibit 61 is a true and correct copy of U.S. Patent No. 4,667,016 (Lai et al.).

64. Exhibit 62 is a true and correct copy of U.S. Patent No. 4,703,008.

65. Exhibit 63 is a true and correct copy of *Amgen v. ITC*, 902 F.3d 1532 (Fed. Cir. 1990).

66. Exhibit 64 is a true and correct copy of Applicant's Amendment and Remarks Under 37 C.F.R. §§ 1.111 and 1.115 in the '298 File History (Paper 15), dated March 11, 1987 (without exhibits). (AM-ITC 00873616-43).

67. Exhibit 65 is a true and correct copy of portions of CHARLES W. RIVISE & A.D. CAESAR, INTERFERENCE LAW AND PRACTICE, Vol. I § 6 (Michie Co., 1940).

68. Exhibit 66 is a true and correct copy of portions of the March 2, 2007 deposition transcript of Michael Borun.

69. Exhibit 67 is a true and correct copy of an Associate Power of Attorney filed in the '179 File History (Paper 2) on February 9, 1988. (AM-ITC 00953131-33).

70. Exhibit 68 is a true and correct copy of the Reply By Senior Party Lin to the Opposition of Junior Party Fritsch Et Al. to Motions of Senior Party Lin to Terminate Interferences, filed in the '096 and '097 Interferences on January 25, 1990. (AM-ITC 00328341-51).

71. Exhibit 69 is a true and correct copy of MPEP § 2002.02 and § 2002.03 (5th ed. Rev. 3, May 1986).

72. Exhibit 70 is a true and correct copy of *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737 (Bd. Pat. App. & Interf. 1992).

73. Exhibit 71 is a true and correct copy of MPEP § 2001.05 (5th ed. Rev. 3, May 1986).

74. Exhibit 72 is a true and correct copy of a Statement of Grounds submitted on October 8, 1992 by Amgen in the EP 411 678 Opposition Proceedings.

75. Exhibit 73 is a true and correct copy of MPEP § 804 (8th ed., Rev. 5, Aug. 2006).

76. Exhibit 74 is a true and correct copy of a Notice of Allowability in the '179 File History (Paper 46), mailed on February 6, 1995. (AM-ITC 00953708).

77. Exhibit 75 is a true and correct copy of an Amendment Under Rule 116 in the '178 File History (Paper 19), dated January 10, 1990. (AM-ITC 00941211-20).

78. Exhibit 76 is a true and correct copy of an Office Action in the '179 File History (Paper 29), mailed on September 1, 1993. (AM-ITC 00953590-601).

79. Exhibit 77 is a true and correct copy of an Office Action in the '179 File History (Paper 34), mailed on February 15, 1994. (AM-ITC 00953649-56).

80. Exhibit 78 is a true and correct copy of Miyake *et al*, "Purification of Human Erythropoietin" (1977). (AM-ITC 00941138-44).

81. Exhibit 79 is a true and correct copy of Belalcazar, V. *et al.* Electrophoresis 27:4387-4395 (2006).
82. Exhibit 80 is a true and correct copy of U.S. Patent No. 5,621,080.
83. Exhibit 81 is a true and correct copy of a Preliminary Amendment in the '874 File History (Paper 37), dated June 13, 1994. (AM-ITC 00941451-54).
84. Exhibit 82 is a true and correct copy of an undated Notice (III) By Lin Under 37 C.F.R. § 1.682(a) in the '096, '097 and '334 Interferences containing the Initial Determination of the ALJ in Inv. No. 337-TA-281. (AM-ITC 00900525-640).
85. Exhibit 83 is a true and correct copy of a Notice (III) By Lin Under 37 C.F.R. § 1.682(a) in the '096, '097 and '334 Interferences, served on April 29, 1991. (AM-ITC 00900641-48).
86. Exhibit 84 is a true and correct copy of a Request for Withdrawal of Suspension in the '179 File History, dated May 1, 1989. (AM-ITC 00900823-26).
87. Exhibit 85 is a true and correct copy of an Amendment Under Rule 116 in the '179 File History (Paper 11), dated June 2, 1989. (AM-ITC 00997385-92).
88. Exhibit 86 is a true and correct copy of an Amendment Under Rule 116 in the '178 File History (Paper 11), dated June 2, 1989. (AM-ITC 00941164-72).
89. Exhibit 87 is a true and correct copy of a chart entitled "Lin EPO Patents." (AM-ITC 00906488).
90. Exhibit 88 is a true and correct copy of MPEP § 609.02 (8th ed. Rev. 5, Aug. 2006).
91. Exhibit 89 is a true and correct copy of a communication from the Examiner in the '179 File History (Paper 16), dated December 2, 1988. (AM-ITC 00953282-83).

92. Exhibit 90 is a true and correct copy of a Request for Withdrawal of Suspension in the '179 File History (Paper 20), dated May 1, 1989. (AM-ITC 00953314-524).

93. Exhibit 91 is a true and correct copy of a Declaration of Interference in the '179 File History (Paper 21), mailed on May 8, 1989. (AM-ITC 00953525-28).

94. Exhibit 92 is a true and correct copy of an Interference Digest in the '179 File History (Paper 22). (AM-ITC 00953529-30).

95. Exhibit 93 is a true and correct copy of Search Notes from the '422 Patent File History. (AM-ITC 00899764).

96. Exhibit 94 is a true and correct copy of a Second Preliminary Amendment and Remarks in the '774 File History (Paper 50), dated December 20, 1995. (AM-ITC 00941543-51).

97. Exhibit 95 is a true and correct copy of the '178 application. (AM-ITC 00940939-1074).

98. Exhibit 96 is a true and correct copy of Applicant's Amendment and Reply Under 37 C.F.R. §§ 1.111 and 1.115 in the '178 File History (Paper 6), dated December 1, 1988. (AM-ITC 00941105-18).

99. Exhibit 97 is a true and correct copy of an Amendment in the '178 File History (Paper 15), dated July 11, 1989. (AM-ITC 00941187-97).

100. Exhibit 98 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 18), dated December 20, 1989. (AM-ITC 00941206-10).

101. Exhibit 99 is a true and correct copy of an Office Action in the '178 File History (Paper 4), mailed on June 2, 1988. (AM-ITC 00941089-100).

102. Exhibit 100 is a true and correct copy of Egrie *et al.*, Characterization of Recombinant Monkey and Human Erythropoietin, *Proc. Clin. Biol. Res.* 1985, 191:339-50.

103. Exhibit 101 is a true and correct copy of Egrie *et al.*, Abstract (1984) from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA, October 2, 1984.

104. Exhibit 102 is a true and correct copy of Egrie *et al.*, Presentation (1984) from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA, October 2, 1984. (AM-ITC 01073032-42).

105. Exhibit 103 is a true and correct copy of Egrie, Presentation Transcript "Cloning of Human & Monkey EPO" (1984) from Hemoglobin Switching Meeting, Airlie House, Virginia, September 1984. (AM-ITC 00557610-16).

106. Exhibit 104 is a true and correct copy of portions of the November 23, 1999 deposition transcript of Michael Borun.

107. Exhibit 105 is a true and correct copy of portions of the trial testimony of Michael Borun from September 6, 2000.

108. Exhibit 106 is a true and correct copy of portions of the trial testimony of Michael Borun from February 5, 2002.

109. Exhibit 107 is a true and correct copy of Justice Neuberger's March 21, 2002 opinion in *HMR v. Kirin-Amgen, Inc.* in the High Court of Justice (Chancery Division) (UK). (AM-ITC 10166841-925).

110. Exhibit 108 is a true and correct copy of portions of the trial transcript from *Amgen v. TKT*.

111. Exhibit 109 is a true and correct copy of an Office Action in the '178 File History (Paper 9), mailed on February 10, 1989. (AM-ITC 00941147-60).

112. Exhibit 110 is a true and correct copy of an Office Action in the '178 File History (Paper 13), mailed on June 20, 1989. (AM-ITC 00941175-83).

113. Exhibit 111 is a true and correct copy of WO 86/03520.

114. Exhibit 112 is a true and correct copy of a Preliminary Amendment in the '874 File History (Paper 45), dated June 7, 1995. (AM-ITC 00941535-57)

115. Exhibit 113 is a true and correct copy of MPEP § 704.01 (5th ed., Rev. 6, Oct. 1987).

116. Exhibit 114 is a true and correct copy of an undated Notice of Allowability in the '774 File History (Paper 52). (AM-ITC 00941561-66).

117. Exhibit 115 is a true and correct copy of a June 6, 1997 Notice of Allowability in the '556 File History (Paper 9). (AM-ITC 00868157-61).

118. Exhibit 116 is a true and correct copy of a Declaration of Interference in the '178 File History (Paper 22). (AM-ITC 00941228-35).

119. Exhibit 117 is a true and correct copy of an Interference Digest in the '178 File History (Paper 23). (AM-ITC 00941236-37).

120. Exhibit 118 is a true and correct copy of a Declaration of Thomas Strickland, submitted in the '334 Interference, dated April 5, 1990. (AM-ITC 00339452-64).

121. Exhibit 119 is a true and correct copy of a Declaration of Jeffrey Browne, submitted in the '334 Interference, dated March 18, 1991. (AM-ITC 00361603-27).

122. Exhibit 120 is a true and correct copy of an October 5, 1998 PTO Initiative, "Changes to Implement the Patent Business Goals," Vol. 63, No. 192, pp. 53498-530.

123. Exhibit 121 is a true and correct copy of portions of the June 27, 2007 deposition transcript of Stephen Kunin.

124. Exhibit 122 is a true and correct copy of Eschbach *et al.*, Correction of the Anemia of End-Stage Renal Disease with Recombinant Human Erythropoietin, *NEJM* 316:73-78 (1987) (Egrie, co-author).

125. Exhibit 123 is a true and correct copy of Vapnek *et al.*, "Comparative Studies of Natural and Recombinant Erythropoietin," *Banbury Reports 29:Therapeutic Peptides and Proteins*, 241-56 (1988). (AM-ITC 00580141-56).

126. Exhibit 124 is a true and correct copy of portions of the April 15, 1991 deposition transcript of Joan Egrie.

127. Exhibit 125 is a true and correct copy of the Reply Of Opponent II, Kirin-Amgen, Inc., To The Response Of the Patentee, Genetics Institute, Inc., In the Opposition To EP 209 539. (AM-ITC 00312411-72).

128. Exhibit 126 is a true and correct copy of a Declaration of Thomas Heckler, dated May 19, 1992. (AM-ITC 00311601-18).

129. Exhibit 127 is a true and correct copy of a Declaration of Eugene Goldwasser, dated January 23, 1993. (AM-ITC 01009089-129).

130. Exhibit 128 is a true and correct copy of a letter from Richard J. Grochala to Stuart Watt, dated October 12, 1993, with attachments. (AM-ITC 00312283-92).

131. Exhibit 129 is a true and correct copy of a Terminal Disclaimer in the '381 File History (Paper 8), dated December 20, 1996. (AM-ITC 00898338-41).

132. Exhibit 130 is a true and correct copy of the February 20, 2007 Third Party Marshall, Gerstein & Borun LLP's Objections and Responses to Subpoena *Ad Testificandum* and *Duces Tecum*, Objections and Response to Request No. 1.

133. Exhibit 131 is a true and correct copy of a March 27, 2007 Letter from Ross to Rycroft.

134. Exhibit 132 is a true and correct copy of portions of Amgen's Product License Application. (AM-ITC 00092249-60; AM-ITC 00092850-81).

135. Exhibit 133 is a true and correct copy of Physician's Desk Reference (44th ed. 1990) at 616.

136. Exhibit 134 is a true and correct copy of Amgen's June 1994 Product Label for Epogen[®]. (AM-ITC 00601553-60).

137. Exhibit 135 is a true and correct copy of the March 9, 2007 Product Labels for Epogen[®] and Procrit[®] available at <http://www.accessdata.fda.gov>.

138. Exhibit 136 is a true and correct copy of portions of Amgen's Notice of Claimed Investigational Exemption for Recombinant-Human Erythropoietin (r-HuEPO). (AM-ITC 00092112-37; AM-ITC 00091216-17).

139. Exhibit 137 is a true and correct copy of an Office Action in the '298 File History (Paper 17), dated June 18, 1987. (R008892042-48).

140. Exhibit 138 is a true and correct copy of Applicant's Amendment and Reply Under 37 C.F.R. §§ 1.111 and 1.115 in the '298 File History (Paper 20), dated July 8, 1987. (R008892053-75).

141. Exhibit 139 is a true and correct copy of an Examiner Interview Summary Record in the '298 File History (Paper 21), dated July 30, 1987. (R008892076).

142. Exhibit 140 is a true and correct copy of portions of Lab Notebook 448. (AM-ITC 00052045).

143. Exhibit 141 is a true and correct copy of a January 13, 1984 letter from Dr. Egrie to Dr. Gaylis. (AM-ITC 00057704).

144. Exhibit 142 is a true and correct copy of handwritten notes. (AM-ITC 00057723-24).

145. Exhibit 143 is a true and correct copy of handwritten notes. (AM-ITC 00057735).

146. Exhibit 144 is a true and correct copy of a draft article by Drs. Gaylis, Ascensao, Zanjani, Egrie, Fraley and Bronson. (AM-ITC 00057708-18).

147. Exhibit 145 is a true and correct copy of a February 12, 1985 letter from Dr. Gaylis to Dr. Egrie enclosing a draft manuscript. (AM-ITC 00057688-701).

148. Exhibit 146 is a true and correct copy of a memo written by Drs. Gaylis, Egrie, Goldwasser, Vasella, Fraley and Bronson. (AM-ITC 00057687).

149. Exhibit 147 is a true and correct copy of letters from Dr. Gaylis to Dr. Goldwasser and accompanying memorandum. (FG 000012-21).

150. Exhibit 148 is a true and correct copy of a November 6, 1986 letter from David Smith to David Bronson. (FG 000048).

151. Exhibit 149 is a true and correct copy of Gaylis *et al.*, "In Vitro Models of Human Testicular Germ-Cell Tumors", *World J. Urol.*, 2:2-5 (1984).

152. Exhibit 150 is a true and correct copy of an abstract by Drs. Ascensao, Gaylis, Fraley, Bronson and Zanjani, entitled "Inducible Production of Erythropoietin By A Human Yolk Sac Tumor Line." (AM-ITC 00057739).

153. Exhibit 151 is a true and correct copy of a November 30, 1982 Abstract Reproduction Form by Dr. Ascensao. (FG 000051).
154. Exhibit 152 is intentionally left blank.
155. Exhibit 153 is a true and correct copy of Ascensao *et al.*, "Erythropoietin Production by a Human Testicular Germ Cell Line", *Blood* 62(5):1132-34 (1983).
156. Exhibit 154 is a true and correct copy of portions of the March 29, 2007 deposition transcript of Stephen Elliot.
157. Exhibit 155 is a true and correct copy of U.S. Patent No. 5,441,868.
158. Exhibit 156 is a true and correct copy of EP 0 093 619.
159. Exhibit 157 is a true and correct copy of a February 21, 1984 Genentech Press Release, accessible at <http://www.gene.com/gene/news/press-releases>.
160. Exhibit 158 is a true and correct copy of a November 13, 1987 FDA Press Release, accessible at <http://www.fda.gov/bbs/topics/NEWS/NEW00191.html>.
161. Exhibit 159 is a true and correct copy of an Office Action in the '179 File History (Paper 9), mailed on August 3, 1988. (AM-ITC 00953226-31)
162. Exhibit 160 is a true and correct copy of U.S. Patent No. 4,766,075.
163. Exhibit 161 is a true and correct copy of an Information Disclosure Statement in the '179 File History (Paper 15), dated September 26, 1988. (AM-ITC 00953279-81).
164. Exhibit 162 is a true and correct copy of an undated Notice of Allowability in the '179 File History. (AM-ITC 00953308).
165. Exhibit 163 is a true and correct copy of a Notice of Allowability with an illegible date in the '381 File History (Paper 12). (AM-ITC 00898389-90).

166. Exhibit 164 is a true and correct copy of U.S. Patent No. 4,966,843 (McCormick *et al.*).

167. Exhibit 165 is a true and correct copy of U.S. Serial No. 438,991.

168. Exhibit 166 is a true and correct copy of a September 6, 1984 Declaration Under 37 C.F.R. § 1.131 in the '843 File History.

169. Exhibit 167 is a true and correct copy of MPEP § 706.02 (5th ed., Rev. 6, Oct. 1987).

170. Exhibit 168 is a true and correct copy of portions of a November 6, 1997 deposition transcript of Stuart Watt. (AM-ITC 00892909-39).

171. Exhibit 169 is a true and correct copy of portions of a May 24, 1989 deposition transcript of George Rathmann.

172. Exhibit 170 is a true and correct copy of U.S. Patent No. 5,756,349.

173. Exhibit 171 is a true and correct copy of handwritten notes regarding RIA. (AM-ITC 00551000).

174. Exhibit 172 is a true and correct copy of an October 7, 1985 letter from Tatsuhiko Kaneko to Joan Egrie, with attachments. (AM-ITC 00550776-816).

175. Exhibit 173 is a true and correct copy of an October 5, 1984 memo from D. Vapnek to recipients at Amgen, with related attachments. (AM-ITC 00061675-706).

176. Exhibit 174 is a true and correct copy of a packet of materials regarding RIA, including handwritten notes dated November 14, 1984, a December 11, 1984 letter from Mamoru Kubota to Joan Egrie, additional data and additional letters. (AM-ITC 00550986-1044).

177. Exhibit 175 is a true and correct copy of MPEP § 2004 (5th ed. Rev. 3, May 1986).
178. Exhibit 176 is a true and correct copy of MPEP § 2004 (8th ed. Rev. 5, Aug. 2006).
179. Exhibit 177 is a true and correct copy of a March 15, 1990 memo from George Rathmann to Dan Vapnek. (AM-ITC 00558618-20).
180. Exhibit 178 is a true and correct copy of a July 24, 1990 memo from George Rathmann to Drs. Egrie, Browne, Strickland and Vapnek, as well as Mr. Odre, among other Amgen recipients. (AM-ITC 00594730-735).
181. Exhibit 179 is a true and correct copy of Amgen's Amended Complaint against Hoechst Marion Roussel, Inc., dated October 7, 1999. (AM-ITC 00823572-90).
182. Exhibit 180 is a true and correct copy of MPEP § 2001.06(b) (5th ed. Rev. 3, May 1986).
183. Exhibit 181 is a true and correct copy of MPEP § 2001.01 (8th ed. Rev. 5, Aug. 2006).
184. Exhibit 182 is a true and correct copy of U.S. Gen. Accounting Office, GAO-RCED-89-120BR, Biotechnology, Backlog of Patent Applications, at 20 (1989).
185. Exhibit 183 is a true and correct copy of an Examiner Interview Summary Record in the '178 File History (Paper 51), dated March 14, 1996. (AM-ITC 00941552-53).
186. Exhibit 184 is a true and correct copy of U.S. Patent No. 5,955,422.
187. Exhibit 185 is a true and correct copy of a Preliminary Amendment in the '741 File History (Paper 2), dated November 6, 1990. (AM-ITC 00899075-87).

188. Exhibit 186 is a true and correct copy of a November 1, 1990 memorandum from S. Hershenson and N.E. Gabriel to J. Browne, K. Chen, J. Egrie, B.W. Hendren, S. Odre, C. Pitt, K. Retterson, T. Strickland, D. Vapnek, M. Vincent, K. Wiltsey. (AM-ITC 00097004-18).

189. Exhibit 187 is a true and correct copy of an Amendment Under Rule 1.116 in the '197 File History (Paper 18), dated December 20, 1993. (AM-ITC 00899150-54).

190. Exhibit 188 is a true and correct copy of an Examiner Interview Summary Record in the '197 File History (Paper 17), dated November 23, 1993. (AM-ITC 00899148-49).

191. Exhibit 189 is a true and correct copy of Garcia, JF, and JC Schooley, "Disassociation of Erythropoietin from Erythropoietin-Antierythropoietin Complex," *Proc. Soc. Biol. Med.* 138:213-215 (1971).

192. Exhibit 190 is a true and correct copy of a September 17, 1984 memo from D. Vapnek to J. Fenno and N. Stebbing. (AM-ITC 00084770-80).

193. Exhibit 191 is a true and correct copy of a December 3, 1984 memo from Joan Egrie and Jim Fenno to numerous Amgen recipients. (AM-ITC 00557514-27).

194. Exhibit 192 is a true and correct copy of a January 11, 1984 letter from Michael Borun to Eugene Goldwasser. (AM-ITC 00954202).

195. Exhibit 193 is a true and correct copy of a September 24, 1990 memo from Joan Egrie to J. Browne, E. Gabriel, S. Odre, T. Strickland and D. Vapnek. (AM-ITC 00554114-25).

196. Exhibit 194 is a true and correct copy of an October 31, 1990 memo from Joan Egrie to J. Browne, E. Gabriel, S. Hershenson, S. Odre and T. Strickland. (AM-ITC 00573885-903).

197. Exhibit 195 is a true and correct copy of an Information Disclosure Statement and accompanying PTO-1449 in the '197 File History (Paper 34), dated April 28, 1999. (AM-ITC 00899477-515).

198. Exhibit 196 is a true and correct copy of an Office Action in the '197 File History (Paper 20), mailed on June 1, 1994. (AM-ITC 00899157-61).

199. Exhibit 197 is a true and correct copy of a Request for Reconsideration in the '197 File History (Paper 23), dated December 1, 1994. (AM-ITC 00899169-75).

200. Exhibit 198 is a true and correct copy of a February 6, 1984 letter from Joseph Baron to the National Center for Drugs and Biologics. (AM-ITC 00245727-29).

201. Exhibit 199 is a true and correct copy of a Grant Application by Dr. Goldwasser, dated August 31, 1984. (AM-ITC 00849306-41).

202. Exhibit 200 is a true and correct copy of an Amendment in the '197 File History (Paper 33), dated April 28, 1999. (AM-ITC 00899469-75).

203. Exhibit 201 is a true and correct copy of a September 10, 1985 memo from Dr. Browne to Dr. Vapnek. (AM-ITC 00932278-85).

204. Exhibit 202 is a true and correct copy of Garcia, "Radioimmunoassay of erythropoietin: circulating levels in normal and polycythemic human beings", *J. Lab. Clin. Med.*, 99:5 624-635 Apr. (1982). (AM-ITC 00478389-400).

205. Exhibit 203 is a true and correct copy of Yalow, R.S. and Berson, S.A., "Immunoassay of Endogenous Plasma Insulin in Man," *J. Clin. Invest.* 39, 1157-75. (1960).

206. Exhibit 204 is a true and correct copy of Yalow, R. "Radioimmunoassay: A Probe for Fine Structure of Biological Systems", Nobel Lecture, pp. 447-68 (12/8/77).

207. Exhibit 205 is intentionally left blank.

208. Exhibit 206 is a true and correct copy of Garcia, J. F. "Assays for Erythropoietin" *in* *Kidney Hormones* (1977) vol. 2, pp. 7-35.

209. Exhibit 207 is a true and correct copy of Clemons, G.K. (1988) Comparison of Radioimmunoassay and Bioassays of Erythropoietin, *in* REGULATION OF ERYTHROPOIESIS: SYMPOSIUM ON ERYTHROPOIESIS 363-374.

210. Exhibit 208 is a true and correct copy of Garcia, J.F. "Radioimmunoassay of Human Plasma Erythropoietin" *in*: Regulation of Erythropoiesis: 1st International Conference on Hematopoiesis (1971), pp. 132-153.

211. Exhibit 209 is a true and correct copy of U.S. Patent No. 4,254,095.

212. Exhibit 210 is a true and correct copy of Sherwood and Goldwasser, "A radioimmunoassay for erythropoietin," *Blood* (1979) 54(4), pp. 885-893 (1979).

213. Exhibit 211 is a true and correct copy of Garcia et al, "Radioimmunoassay of erythropoietin," *Blood Cells* (1979) 5(3), PP. 405-419.

214. Exhibit 212 is a true and correct copy of Zaroulis et al., "A microimmunofluorescent assay to detect human granulocyte antigens & antibodies." *Am. J. Hematol.* (1981) 10, pp. 65-73.

215. Exhibit 213 is a true and correct copy of Rege et al., "A radioimmunoassay for erythropoietin: serum levels in normal human subjects and patients with hemopoietic disorders," *J. Lab. Clin. Med.* (1982) 100(6), pp. 829-843.

216. Exhibit 214 is a true and correct copy of Sytkowski and Sue, "A novel radioimmunoassay for human erythropoietin using a synthetic NH₂ terminal peptide and antipeptide antibodies," *J. Immunol. Methods* (1983) 69(2), pp. 181-186.

217. Exhibit 215 is a true and correct copy of Egrie et al., "Development of radioimmunoassays for human erythropoietin using recombinant erythropoietin as tracer and immunogen," *J. Immunol. Methods* (1987) 99(2), pp. 235-241.

218. Exhibit 216 is a true and correct copy of Goldwasser, *J. Biol. Chem.*, vol. 249, pp. 4202-06 (1974).

219. Exhibit 217 is a true and correct copy of White et al., "Studies in erythropoietin" *Recent Prog. Horm. Res.*, 16:219, 1960.

220. Exhibit 218 is a true and correct copy of Goldwasser, "Studies on Erythropoiesis," *J. Lab. Clin. Med.* 50(4):534-42 (1958).

221. Exhibit 219 is a true and correct copy of Cotes and Bangham, "The international reference preparation of erythropoietin," (1966) *Bull. World Health Org* 35(5), 751-760.

222. Exhibit 220 is a true and correct copy of Annable et al., "The Second International Reference Preparation of Erythropoietin, Human, Urinary, For Bioassay." *Bull. World Health Org.* (1972), 47(1), pp. 99-112

223. Exhibit 221 is a true and correct copy of a September 20, 1984 letter from Dr. Egrie to Drs. Suzuki and Sudo. (AM-ITC 00134725).

224. Exhibit 222 is a true and correct copy of Storrington and Gaines Das, "The International standard for recombinant DNA-derived erythropoietin," *J. of Endocrinology*, Vol. 134, pp. 459-84 (1992).

225. Exhibit 223 is a true and correct copy of a June 21-22, 1982 Report of the Erythropoietin Assay Workshop. (UCH00002512-17).

226. Exhibit 224 is a true and correct copy of the February 14, 2007 deposition transcript of Dr. Eugene Goldwasser.

227. Exhibit 225 is a true and correct copy of a December 11, 1984 memo from Jeff Browne. (AM-ITC 00134889-92).

228. Exhibit 226 is a true and correct copy of Defendant's Responses and Objections to Plaintiff Amgen's Third Set of Interrogatories to Defendants (No. 26) (April 2, 2007).

229. Exhibit 227 is a true and correct copy of MPEP § 2001.04 (5th ed. Rev. 14, 1992).

230. Exhibit 228 is a true and correct copy of MPEP § 2363.02 (5th ed. Rev. 13, Nov. 1989).

231. Exhibit 229 is a true and correct copy of MPEP § 2363.02 (8th ed., Aug. 2001).

232. Exhibit 230 is a true and correct copy of MPEP § 2301 (8th ed. Rev. 5, Aug. 2006).

233. Exhibit 231 is a true and correct copy of MPEP § 706 (5th ed. Rev. 6, Oct. 1987).

234. Exhibit 232 is a true and correct copy of MPEP § 706 (8th ed. Rev. 5, Aug. 2006).

235. Exhibit 233 is a true and correct copy of MPEP § 708.02 (5th ed. Rev 6, Oct. 1987).

236. Exhibit 234 is a true and correct copy of MPEP § 708.02 (8th ed. Rev. 5, Aug. 2006).

237. Exhibit 235 is a true and correct copy of U.S. Patent No. 4,879,272.

238. Exhibit 236 is a true and correct copy of "Guidelines for Reexamination Of Cases In View of In Re Portola Packaging, Inc." 1223 OG 124.

239. Exhibit 237 is a true and correct copy of an Office Action in the '874 File History (Paper 38), mailed on August 16, 1994. (AM-ITC 00941455-66).

240. Exhibit 238 is a true and correct copy of an Office Action in the '874 File History (Paper 43), mailed on May 17, 1995. (AM-ITC 00941522-29).

241. Exhibit 239 is a true and correct copy of a declaration of interference in the '741 File History (Paper 8), mailed on November 20, 1992. (AM-ITC 00899104-07).

242. Exhibit 240 is a true and correct copy of an Interference Digest in the '741 File History (Paper 9). (AM-ITC 00899108-09).

243. Exhibit 241 is a true and correct copy of a Declaration Accompanying Petition to Make Special in the '179 File History, dated April 23, 1986. (AM-ITC 00953142-49).

244. Exhibit 242 is a true and correct copy of portions of U.S. Patent No. 5,618,698.

245. Exhibit 243 is a true and correct copy of a November 2, 1990 memorandum from George Rathmann. (AM-ITC 00558658-76).

246. Exhibit 244 is a true and correct copy of a February 14, 1986 letter from Joan Egrie. (AM-ITC 00550541-44).

247. Exhibit 245 is a true and correct copy of additional portions of the March 27, 2007 deposition transcript of Dr. Joan Egrie.

248. Exhibit 246 is a true and correct copy of additional portions of the March 28, 2007 deposition transcript of Dr. Fu-Kuen Lin.

249. Exhibit 247 is a true and correct copy of an Office Action in the '178 File History (Paper 16), mailed on September 18, 1989. (AM-ITC 00941198-203).

250. Exhibit 248 is a true and correct copy of a Decision on Petition to Make Special in the '179 File History (Paper 5). (AM-ITC 00953191-92).

251. Exhibit 249 is a true and correct copy of a communication from Examiner Schain in the '178 File History (Paper 21). (AM-ITC 00941224-27).

Signed under the penalties of perjury pursuant to 28 U.S.C. Sec. 1746 this 5th day of July, 2007.

/s/ Krista M. Rycroft
Krista M. Rycroft

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Keith E. Toms
Keith E. Toms

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