

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE, LTD,
ROCHE DIAGNOSTICS GMBH,
and HOFFMANN-LA ROCHE INC.

Defendants.

Civil Action No. 05-12237 WGY

U.S. District Judge Young

**DECLARATION OF KEITH E. TOMS IN SUPPORT OF
DEFENDANTS' OPPOSITION TO AMGEN'S MOTION FOR
SUMMARY JUDGMENT OF INFRINGEMENT OF
'422 CLAIM 1, '933 CLAIM 3, AND '698 CLAIM 6**

*Contains Roche Restricted Access Confidential
BLA/IND Information Subject to Protective Order*

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, Massachusetts 02110
Tel. (617) 443-9292

*Counsel for Defendants
F. Hoffmann-La Roche, Ltd,
Roche Diagnostics GmbH, and
Hoffmann-La Roche Inc.*

I, Keith E. Toms, hereby declare under penalty of perjury that:

1. I am an attorney admitted to the Bars of the State of Massachusetts and the United States District Court for the District of Massachusetts and am an associate at Bromberg & Sunstein LLP, and counsel for Defendants in the above-captioned case.

2. I make this declaration in support of Defendants' Opposition To Amgen's Motion For Summary Judgment Of Infringement Of '422 Claim 1, '933 Claim 3, And '698 Claim 6, dated June 29, 2007.

3. Exhibit 1, attached hereto, is a true and correct copy of '178 File History, Application Claims at 49, 97, 101, 102.

4. Exhibit 2, attached hereto, is a true and correct copy of '178 File History, Paper 11, 6/2/89 Amendment at 3-4.

5. Exhibit 3, attached hereto, is a true and correct copy of '178 File History, Paper 13, 6/20/89 Office Action at 3, 5.

6. Exhibit 4, attached hereto, is a true and correct copy of '178 File History, Paper 15, 7/11/89 Amendment at 1, 3-4.

7. Exhibit 5, attached hereto, is a true and correct copy of '178 File History, Paper 17, 12/1/89 Examiner Interview Summary Record.

8. Exhibit 6, attached hereto, is a true and correct copy of '178 File History, Paper 19, 1/10/90 Amendment at 1, 5, 6.

9. Exhibit 7, attached hereto, is a true and correct copy of '178 File History, Paper 32, 4/21/99 Examiner Interview Summary.

10. Exhibit 8, attached hereto, is a true and correct copy of '197 File History, Paper 35, Terminal Disclaimer.

11. Exhibit 9, attached hereto, is a true and correct copy of '178 File History, Paper 4, 6/2/86 Office Action at 3-5.

12. Exhibit 10, attached hereto, is a true and correct copy of '178 File History, Paper 6, 12/1/88 Amendment and Reply at 3, 8-9.

13. Exhibit 11, attached hereto, is a true and correct copy of '178 File History, Paper 9, 2/10/89 Office Action.

14. Exhibit 12, attached hereto, is a true and correct copy of '179 File History, Paper 1.

15. Exhibit 13, attached hereto, is a true and correct copy of '179 File History, Paper 14, 9/27/88 Reply.

16. Exhibit 14, attached hereto, is a true and correct copy of '179 File History, Paper 29, 9/1/93 Office Action at 9-10.

17. Exhibit 15, attached hereto, is a true and correct copy of '179 File History, Paper 33, 1/3/94 Amendment and Response at 2 , 5, 11.

18. Exhibit 16, attached hereto, is a true and correct copy of '179 File History, Paper 8, 5/24/88 Second Preliminary Amendment at 3-4, 6-10, 15-19.

19. Exhibit 17, attached hereto, is a true and correct copy of '197 File History, Paper 2, 11/6/90 Preliminary Amendment at 8.

20. Exhibit 18, attached hereto, is a true and correct copy of '197 File History, Paper 20, 6/1/94 Office Action at 3, 4.

21. Exhibit 19, attached hereto, is a true and correct copy of '197 File History, Paper 26, 3/31/95 Letter.

22. Exhibit 20, attached hereto, is a true and correct copy of '197 File History, Paper 33, 4/28/99 Amendment at 3-4.

23. Exhibit 21, attached hereto, is a true and correct copy of '197 File History, Paper 4, 4/6/92 Office Action at 2.

24. Exhibit 22, attached hereto, is a true and correct copy of '381 File History, Paper 1, Application.

25. Exhibit 23, attached hereto, is a true and correct copy of '381 File History, Paper 3a, 6/6/95 Continuing Application Transmittal.

26. Exhibit 24, attached hereto, is a true and correct copy of '381 File History, Paper 7, 12/11/96 Interview Summary.

27. Exhibit 25, attached hereto, is a true and correct copy of '381 File History, Paper 8, 12/20/96 Terminal Disclaimer;.

28. Exhibit 26, attached hereto, is a true and correct copy of '381 File History, Paper 9, 12/20/96 Second Preliminary Amendment at 7-8, 10.

29. Exhibit 27, attached hereto, is a true and correct copy of '398 patent File History, Response to Final Office Action and Amendment (6/24/02) at 5.

30. Exhibit 28, attached hereto, is a true and correct copy of '741 File History, Application Claims at 102.

31. Exhibit 29, attached hereto, is a true and correct copy of '741 File history, Paper 1, 11/6/90 Application.

32. Exhibit 30, attached hereto, is a true and correct copy of '741 File History, Paper 2, 11/6/90 Preliminary Amendment at 2, 4, 5, 6 and 8.

33. Exhibit 31, attached hereto, is a true and correct copy of '741 File History, Paper 4, 4/6/92 Office Action.

34. Exhibit 32, attached hereto, is a true and correct copy of '774 File History, Paper 45, 6/7/95 Preliminary Amendment at 2.

35. Exhibit 33, attached hereto, is a true and correct copy of '774 File History, Paper 50, 12/20/95 Second Preliminary Amendment at 2.

36. Exhibit 34, attached hereto, is a true and correct copy of '874 File History, Paper 37, 6/13/94 Preliminary Amendment.

37. Exhibit 35, attached hereto, is a true and correct copy of '197 File History, Paper 23, 12/1/94 Request for Reconsideration.

38. Exhibit 36, attached hereto, is a true and correct copy of '197 File History, Paper 25, 3/3/95 Amendment and Declaration of Richard D. Cummings, Ph.D.

39. Exhibit 37, attached hereto, is a true and correct copy of 12/20/99 Expert Statement of Harvey F. Lodish, Ph.D., at paragraph 124.

40. Exhibit 38 is intentionally omitted.

41. Exhibit 39 is intentionally omitted.

42. Exhibit 40, attached hereto, is a true and correct copy of 4,703,008.

43. Exhibit 41 is intentionally omitted.

44. Exhibit 42, attached hereto, is a true and correct copy of 5,153,265.

45. Exhibit 43, attached hereto, is a true and correct copy of 5,441,868.

46. Exhibit 44, attached hereto, is a true and correct copy of 5,547,933.

47. Exhibit 45, attached hereto, is a true and correct copy of 5,618,698.

48. Exhibit 46, attached hereto, is a true and correct copy of 5,856,298.

49. Exhibit 47, attached hereto, is a true and correct copy of 5,955,422.

50. Exhibit 48, attached hereto, is a true and correct copy of 5/11/07 Cords Report ¶¶ 24-33.

51. Exhibit 49, attached hereto, is a true and correct copy of 6,399,333.

52. Exhibit 50, attached hereto, is a true and correct copy of 6,471,500.
53. Exhibit 51, attached hereto, is a true and correct copy of 6,583,272.
54. Exhibit 52, attached hereto, is a true and correct copy of 6,586,398.
55. Exhibit 53, attached hereto, is a true and correct copy of 7,217,689.
56. Exhibit 54 is intentionally omitted.
57. Exhibit 55 is intentionally omitted.
58. Exhibit 56, attached hereto, is a true and correct copy of Abuchowski et al. (1977) at 3579.
59. Exhibit 57, attached hereto, is a true and correct copy of Alberts (1983) at 92.
60. Exhibit 58, attached hereto, is a true and correct copy of AM 44 0004799-834 at 809.
61. Exhibit 59, attached hereto, is a true and correct copy of AM 44 0197792.
62. Exhibit 60, attached hereto, is a true and correct copy of AM 44 0445251-5274 at 61.
63. Exhibit 61, attached hereto, is a true and correct copy of AM44 0003879.
64. Exhibit 62, attached hereto, is a true and correct copy of AM44 0004809.
65. Exhibit 63, attached hereto, is a true and correct copy of AM44 004799-AM44 0004834: "How Do Physical Changes in ESPs Affect Biological Activity".
66. Exhibit 64, attached hereto, is a true and correct copy of AM44 0156801-0156884 at 811.
67. Exhibit 65, attached hereto, is a true and correct copy of AM44 0230737-67 at 745.
68. Exhibit 66 is intentionally omitted.
69. Exhibit 67, attached hereto, is a true and correct copy of AM44 0825645.
70. Exhibit 68, attached hereto, is a true and correct copy of AM44 0897376-82.
71. Exhibit 69, attached hereto, is a true and correct copy of AM44 1591670-1679.
72. Exhibit 70, attached hereto, is a true and correct copy of AM67 01078325-330 at 327.

73. Exhibit 71 is intentionally omitted.
74. Exhibit 72, attached hereto, is a true and correct copy of Amgen I at 91.
75. Exhibit 73, attached hereto, is a true and correct copy of Amgen Inc.'s Response to Defendants' Claim Construction Brief filed 3/19/07 323.
76. Exhibit 74, attached hereto, is a true and correct copy of AM-ITC 00974613 (Amgen Patent Tree).
77. Exhibit 75, attached hereto, is a true and correct copy of Amgen Supplemental Response to Rogg, 8, 2/10/07.
78. Exhibit 76, attached hereto, is a true and correct copy of *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 283-303 (D. Mass. 2004).
79. Exhibit 77, attached hereto, is a true and correct copy of Amgen's Epogen Label.
80. Exhibit 78, attached hereto, is a true and correct copy of Amgen's Supp. Response to Rogg 8, dated 2/9/07 at 26.
81. Exhibit 79, attached hereto, is a true and correct copy of AM-ITC 00052992-95.
82. Exhibit 80, attached hereto, is a true and correct copy of AM-ITC 00102090-105.
83. Exhibit 81, attached hereto, is a true and correct copy of AM-ITC 00595293.
84. Exhibit 82, attached hereto, is a true and correct copy of AM-ITC 00596039-042.
85. Exhibit 83, attached hereto, is a true and correct copy of AM-ITC 00941090-1099, at 1094.
86. Exhibit 84, attached hereto, is a true and correct copy of AM-ITC-00087147-7158.
87. Exhibit 85, attached hereto, is a true and correct copy of AM-ITC-00900034-39.
88. Exhibit 86, attached hereto, is a true and correct copy of AM-ITC-00903447-56.
89. Exhibit 87, attached hereto, is a true and correct copy of AM-ITC-00929860-862.
90. Exhibit 88, attached hereto, is a true and correct copy of AM-ITC-01072476-2501.
91. Exhibit 89, attached hereto, is a true and correct copy of AM-ITC 00592757.
92. Exhibit 90, attached hereto, is a true and correct copy of Banga (2006) at 205.

93. Exhibit 91, attached hereto, is a true and correct copy of Beauchamp et al. (1983) at 31.
94. Exhibit 92, attached hereto, is a true and correct copy of Benet Report I ¶¶ 30-32.
95. Exhibit 93, attached hereto, is a true and correct copy of Benet Tr. 197:7-15, 246:11-13.
96. Exhibit 94, attached hereto, is a true and correct copy of Boone Tr. (3/30/07) 28:11-22 , 31:5-12, 46:20-22, 93:1-10, 94:21-95:4, 96:12-21 24:22-26:1, 31:6-11, 46:20-22, 76:6 - 77:16, 92:24 - 93:3, 94:14 - 96:24, 159:16-24.
97. Exhibit 95, attached hereto, is a true and correct copy of Bradshaw Expert Report 6/1/07 ¶¶ 17, 20.
98. Exhibit 96, attached hereto, is a true and correct copy of Bradshaw Tr. pp. 272:20-277:18, 76:2-10, 16:1-25.
99. Exhibit 97, attached hereto, is a true and correct copy of Cheetham et al. (1998) at 861.
100. Exhibit 98 is intentionally omitted.
101. Exhibit 99, attached hereto, is a true and correct copy of Cram & Cram, "The Essence of Organic Chemistry" 273 (Addison-Wesley Publishing Co. 1978)).
102. Exhibit 100, attached hereto, is a true and correct copy of Declaration of Thomas Wayne Strickland (11/30/88 ¶¶ 5, 6, 11).
103. Exhibit 101, attached hereto, is a true and correct copy of Delgado (1992) at 274, 276.
104. Exhibit 102, attached hereto, is a true and correct copy of Delivery of Protein and Peptide Drugs in Cancer (2006) Chapter 4 pp. 76-77.
105. Exhibit 103, attached hereto, is a true and correct copy of Delorme et al. (1992).
106. Exhibit 104, attached hereto, is a true and correct copy of Elliot Tr., 3/29/07, pp. 198:12-199:11.
107. Exhibit 105 is intentionally omitted.
108. Exhibit 106, attached hereto, is a true and correct copy of Elliott Depo. Tr. (5/20/98) *Ortho Biotech v. Kirin-Amgen*, 70:22-72:15, 141:6-141:9).
109. Exhibit 107, attached hereto, is a true and correct copy of Elliott et al., *Mapping of the Active Site of Recombinant Human Erythropoietin*, Blood, Vol. 89, No. 2, pp. 493-502 (1997)).

110. Exhibit 108, attached hereto, is a true and correct copy of Elliott *Ortho* Tr. 10/15/98 at 3354:22-3355:17, 3421:8-3424:20, 3636:1-10.

111. Exhibit 109, attached hereto, is a true and correct copy of Elliott Tr. (3/29/07) 13:5-16; 23:16-19; 24:13-15; 24:23-25:2, 201:25-202:22, 216:16-220:12, 229:4-232:21, 237:13-241:24.

112. Exhibit 110, attached hereto, is a true and correct copy of Elliott, S.G., New Molecules and Formulations of Recombinant Human Erythropoietin, *in* ERYTHROPOIETINS AND ERYTHROPOIESIS 241-58 (G. Molineux et al., eds. 2003)).

113. Exhibit 111, attached hereto, is a true and correct copy of EPOGEN Label issued 03/09/07 p. 25.

114. Exhibit 112 is intentionally omitted.

115. Exhibit 113, attached hereto, is a true and correct copy of Exhibit 31 to its “Memorandum In Support of Amgen Inc.’s Motion for Summary Judgment Of Infringement of ‘422 Claim 1, ‘933 Claim 3, And ‘698 Claim 6.”.

116. Exhibit 114, attached hereto, is a true and correct copy of File History of U.S. Pat. No. 4,703,008, AM-ITC-00873591.

117. Exhibit 115, attached hereto, is a true and correct copy of *Genentech, Inc., v. Boehringer Mannheim GmbH*, 47 F.Supp.2d 91, 95 (D. Mass. 1999).

118. Exhibit 116, attached hereto, is a true and correct copy of Goldwasser et al. (1974) at 4202-4206.

119. Exhibit 117, attached hereto, is a true and correct copy of Goldwasser Tr. 2/14/07, pp. 177:18-178:11).

120. Exhibit 118, attached hereto, is a true and correct copy of Gross & Lodish (2006) Entire Article.

121. Exhibit 119, attached hereto, is a true and correct copy of Gutfreund (1955).

122. Exhibit 120, attached hereto, is a true and correct copy of Halstenson Clin. Pharmacol. Ther. 50: 702-712 (1991).

123. Exhibit 121, attached hereto, is a true and correct copy of Harris & Chess (2003) at 215, 220.

124. Exhibit 122, attached hereto, is a true and correct copy of Harris (2001), 542-549).

125. Exhibit 123, attached hereto, is a true and correct copy of Haselbeck Dep. Tr. 128-129.

126. Exhibit 124, attached hereto, is a true and correct copy of Heatherington *in* ERYTHROPOIETINS AND ERYTHROPOIESIS AT 87 (G. Molineaux et al., eds. 2003)0. .

127. Exhibit 125, attached hereto, is a true and correct copy of <http://www.amgen.com/patients/prca.html>.

128. Exhibit 126, attached hereto, is a true and correct copy of Hynes, Adherence to Guidelines for ESRD Anemia Management 2006.

129. Exhibit 127, attached hereto, is a true and correct copy of ITC-R-BLA-00005515.

130. Exhibit 128, attached hereto, is a true and correct copy of ITC-R-BLA 00000091.

131. Exhibit 129, attached hereto, is a true and correct copy of ITC-R-BLA- 00004032, 4035 .

132. Exhibit 130, attached hereto, is a true and correct copy of ITC-R-BLA-00004271-4275.

133. Exhibit 131, attached hereto, is a true and correct copy of ITC-R-BLA-00004301-4306.

134. Exhibit 132, attached hereto, is a true and correct copy of ITC-R-BLA- 00005580.

135. Exhibit 133, attached hereto, is a true and correct copy of ITC-R-BLA 00007306-00007318.

136. Exhibit 134, attached hereto, is a true and correct copy of AM-ITC 00899473.

137. Exhibit 135, attached hereto, is a true and correct copy of ITC-R-BLA-00004178.

138. Exhibit 136, attached hereto, is a true and correct copy of ITC-R-BLA-00000001-22.

139. Exhibit 137, attached hereto, is a true and correct copy of ITC-R-BLA-00000066 (draft package insert).

140. Exhibit 138, attached hereto, is a true and correct copy of ITC-R-BLA-00000212.

141. Exhibit 139, attached hereto, is a true and correct copy of ITC-R-BLA-00000217.

142. Exhibit 140, attached hereto, is a true and correct copy of ITC-R-BLA-00000248.

143. Exhibit 141, attached hereto, is a true and correct copy of ITC-R-BLA-00000250.

144. Exhibit 142, attached hereto, is a true and correct copy of ITC-R-BLA-00000261.

145. Exhibit 143, attached hereto, is a true and correct copy of ITC-R-BLA-00000309.

146. Exhibit 144, attached hereto, is a true and correct copy of ITC-R-BLA-00000313-327.
147. Exhibit 145, attached hereto, is a true and correct copy of ITC-R-BLA-00000322-325.
148. Exhibit 146, attached hereto, is a true and correct copy of ITC-R-BLA-00000502-506, 511-513.
149. Exhibit 147, attached hereto, is a true and correct copy of ITC-R-BLA-00002808.
150. Exhibit 148, attached hereto, is a true and correct copy of ITC-R-BLA-00003366.
151. Exhibit 149 is intentionally omitted.
152. Exhibit 150, attached hereto, is a true and correct copy of ITC-R-BLA-00003417.
153. Exhibit 151, attached hereto, is a true and correct copy of ITC-R-BLA-00003428-29.
154. Exhibit 152, attached hereto, is a true and correct copy of ITC-R-BLA-00004027.
155. Exhibit 153, attached hereto, is a true and correct copy of ITC-R-BLA-00004028.
156. Exhibit 154, attached hereto, is a true and correct copy of ITC-R-BLA-00004029.
157. Exhibit 155, attached hereto, is a true and correct copy of ITC-R-BLA-00004031.
158. Exhibit 156, attached hereto, is a true and correct copy of ITC-R-BLA-00004032.
159. Exhibit 157, attached hereto, is a true and correct copy of ITC-R-BLA-00004035.
160. Exhibit 158, attached hereto, is a true and correct copy of ITC-R-BLA-00004043.
161. Exhibit 159, attached hereto, is a true and correct copy of ITC-R-BLA-00004046-4051.
162. Exhibit 160, attached hereto, is a true and correct copy of ITC-R-BLA-00004059.
163. Exhibit 161, attached hereto, is a true and correct copy of ITC-R-BLA-00004126.
164. Exhibit 162, attached hereto, is a true and correct copy of ITC-R-BLA-00004178.
165. Exhibit 163, attached hereto, is a true and correct copy of ITC-R-BLA-00004233.
166. Exhibit 164, attached hereto, is a true and correct copy of ITC-R-BLA-00004241-4268.

167. Exhibit 165, attached hereto, is a true and correct copy of ITC-R-BLA-00004247-4256.
168. Exhibit 166, attached hereto, is a true and correct copy of ITC-R-BLA-00004257-4268.
169. Exhibit 167, attached hereto, is a true and correct copy of ITC-R-BLA-00004271-4275.
170. Exhibit 168, attached hereto, is a true and correct copy of ITC-R-BLA-00004296-4316.
171. Exhibit 169, attached hereto, is a true and correct copy of ITC-R-BLA-00004299-300.
172. Exhibit 170, attached hereto, is a true and correct copy of ITC-R-BLA-00004307-4312.
173. Exhibit 171, attached hereto, is a true and correct copy of ITC-R-BLA-00004659.
174. Exhibit 172, attached hereto, is a true and correct copy of ITC-R-BLA-00004660.
175. Exhibit 173, attached hereto, is a true and correct copy of ITC-R-BLA-00004661.
176. Exhibit 174, attached hereto, is a true and correct copy of ITC-R-BLA-00004663-4.
177. Exhibit 175, attached hereto, is a true and correct copy of ITC-R-BLA-00004667.
178. Exhibit 176, attached hereto, is a true and correct copy of ITC-R-BLA-00004680.
179. Exhibit 177, attached hereto, is a true and correct copy of ITC-R-BLA-00004682-4704.
180. Exhibit 178, attached hereto, is a true and correct copy of ITC-R-BLA-00004716.
181. Exhibit 179, attached hereto, is a true and correct copy of ITC-R-BLA-00004722.
182. Exhibit 180, attached hereto, is a true and correct copy of ITC-R-BLA-00004723.
183. Exhibit 181 is intentionally omitted.
184. Exhibit 182 is intentionally omitted.
185. Exhibit 183, attached hereto, is a true and correct copy of ITC-R-BLA-00005616-32.
186. Exhibit 184, attached hereto, is a true and correct copy of ITC-R-BLA-00005656-74.

187. Exhibit 185, attached hereto, is a true and correct copy of ITC-R-BLA-00005770-73.

188. Exhibit 186, attached hereto, is a true and correct copy of ITC-R-BLA-00007081-7124.

189. Exhibit 187, attached hereto, is a true and correct copy of ITC-R-BLA-00007125-7158 Entire Doc.

190. Exhibit 188, attached hereto, is a true and correct copy of ITC-R-BLA-00007159-7206.

191. Exhibit 189, attached hereto, is a true and correct copy of ITC-R-BLA-00007243-255.

192. Exhibit 190 is intentionally omitted.

193. Exhibit 191, attached hereto, is a true and correct copy of ITC-R-BLA-00007256-70.

194. Exhibit 192, attached hereto, is a true and correct copy of ITC-R-BLA-00007267.

195. Exhibit 193, attached hereto, is a true and correct copy of ITC-R-BLA-00007271-90.

196. Exhibit 194, attached hereto, is a true and correct copy of ITC-R-BLA-00007281-3, Figures 1 and 2.

197. Exhibit 195, attached hereto, is a true and correct copy of ITC-R-BLA-00007291-7305.

198. Exhibit 196, attached hereto, is a true and correct copy of ITC-R-BLA-00007310-18 at 15-18, figs. 1 and 2, table 1.

199. Exhibit 197, attached hereto, is a true and correct copy of ITC-R-BLA-00007319-753 at 325, Fig.1, Tables 1 and 2; 326-327, Fig. 2, Tables 3 and 4.

200. Exhibit 198, attached hereto, is a true and correct copy of ITC-R-BLA-00007469-7506 at 7486, 7490.

201. Exhibit 199, attached hereto, is a true and correct copy of ITC-R-BLA-00019402-84.

202. Exhibit 200 is intentionally omitted.

203. Exhibit 201 is intentionally omitted.

204. Exhibit 202, attached hereto, is a true and correct copy of ITC-RBLA-00022202-00022327.

205. Exhibit 203, attached hereto, is a true and correct copy of ITC-R-BLA-0005775-81.
206. Exhibit 204, attached hereto, is a true and correct copy of ITC-R-BLA-00066252-66426 at 282.
207. Exhibit 205, attached hereto, is a true and correct copy of ITC-R-BLA-00075601-802.
208. Exhibit 206, attached hereto, is a true and correct copy of ITC-R-BLA-00084420-84557.
209. Exhibit 207, attached hereto, is a true and correct copy of ITC-R-BLA-00109530-675.
210. Exhibit 208, attached hereto, is a true and correct copy of ITC-R-BLA-00115298-421.
211. Exhibit 209, attached hereto, is a true and correct copy of ITC-R-BLA-00140975-41134.
212. Exhibit 210 is intentionally omitted.
213. Exhibit 211, attached hereto, is a true and correct copy of ITC-R-IND-00064970-981 at 971.
214. Exhibit 212, attached hereto, is a true and correct copy of Jacobs 1985.
215. Exhibit 213, attached hereto, is a true and correct copy of Jarsch (3/27/07) Tr. at 56:8-17.
216. Exhibit 214, attached hereto, is a true and correct copy of Jorgensen and Tirado-Rives Molecular Modeling of Organic and Biomolecular Systems Using BOSS and MCPRO, Comput. Chem. 2005, 26, 1689-1700.
217. Exhibit 215, attached hereto, is a true and correct copy of Karp (2002) at 52-53, 55-62.
218. Exhibit 216, attached hereto, is a true and correct copy of Katre (1993) at 93, 95, 98, 103.
219. Exhibit 217, attached hereto, is a true and correct copy of Kinstler et al. (2002) at 478.
220. Exhibit 218, attached hereto, is a true and correct copy of Klibanov 5/11/07 Expert Report ¶ 116.
221. Exhibit 219, attached hereto, is a true and correct copy of Klibanov Tr. 5/23/07. 153:18-154:13.

222. Exhibit 220, attached hereto, is a true and correct copy of Kozlowski and Harris (2001) at 219-20.

223. Exhibit 221, attached hereto, is a true and correct copy of Krantz and Goldwasser, *Specific Binding of Erythropoietin to spleen cells infected with the anemia strain of Friend virus*, Proc. Natl. Acad. Sci., 81: 7574-7578 (1984).

224. Exhibit 222, attached hereto, is a true and correct copy of Kynclova (1996) at 644.

225. Exhibit 223, attached hereto, is a true and correct copy of Lai 1986.

226. Exhibit 224, attached hereto, is a true and correct copy of Lin *et al.*, "Cloning and expression of the human erythropoietin gene," *PNAS*, 82 7580-7584 (1985).

227. Exhibit 225, attached hereto, is a true and correct copy of Lin Tr. (3/28/07) 91:4-122:25, 304:12-305:5.

228. Exhibit 226, attached hereto, is a true and correct copy of Lin Tr. 6/7/00 at 965:8-14.

229. Exhibit 227, attached hereto, is a true and correct copy of Lodish 4/6/07 Expert Report ¶¶ 24, 31-33, 92, 94-95, 139, 141, 172, 182, 183, 187-89, 192.

230. Exhibit 228, attached hereto, is a true and correct copy of Lodish Dep. Tr., J&J Arb., Jul. 30, 1998 at 110-111.

231. Exhibit 229, attached hereto, is a true and correct copy of Macdougall & Eckardt, "Novel strategies for stimulating erythropoiesis and potential new treatments for anaemia," *Lancet*, 2006, 368:947-953).

232. Exhibit 230, attached hereto, is a true and correct copy of MacDougall (2005) at 436, 439.

233. Exhibit 231, attached hereto, is a true and correct copy of Macdougall Clin J. Am Soc. Nephrol. 1: 1211-1215 (2006).

234. Exhibit 232, attached hereto, is a true and correct copy of Macdougall J. Am Soc Nephrol 10: 2392-2395 (1999).

235. Exhibit 233, attached hereto, is a true and correct copy of Markman Tr.

236. Exhibit 234, attached hereto, is a true and correct copy of Mattison (2001) at 66-67.

237. Exhibit 235, attached hereto, is a true and correct copy of Mayeux, P. et al., *The Erythropoietin Receptor of Rat Erythroid Progenitor Cells; Characterization and Affinity Cross Linkage*, J. Bio. Chem., Vol. 262, No. 29, pp. 13985-13990 (1987)).

238. Exhibit 236, attached hereto, is a true and correct copy of Molineux (2002) at 13-15.

239. Exhibit 237, attached hereto, is a true and correct copy of Molineux Depo. Tr., 3/28/07 at 44-45, 47-48.

240. Exhibit 238, attached hereto, is a true and correct copy of Molineux in "Erythropoietins and Erythropoiesis, Molecular, Cellular, Preclinical and Clinical Biology" at 8, fig. 2).

241. Exhibit 239, attached hereto, is a true and correct copy of Molineux Tr. (3/28/07) 43:19-50:6, 72:1- 72:20.

242. Exhibit 240, attached hereto, is a true and correct copy of Molineux, Anti-Cancer Drugs (2003) at 259-260.

243. Exhibit 241, attached hereto, is a true and correct copy of Molineux, Pharmacotherapy (2003) at 5S.

244. Exhibit 242, attached hereto, is a true and correct copy of Morrison & Boyd (1983) at 2-3, 79, 157.

245. Exhibit 243, attached hereto, is a true and correct copy of MPEP §2173.05(p) (8th ed. Rev. 5, Aug. 2006).

246. Exhibit 244, attached hereto, is a true and correct copy of MPEP §706.03(e) (5th ed. Rev. 6, Oct. 1987).

247. Exhibit 245 is intentionally omitted.

248. Exhibit 246, attached hereto, is a true and correct copy of Ossulund (2003) at 32-33.

249. Exhibit 247, attached hereto, is a true and correct copy of R001507222-225.

250. Exhibit 248, attached hereto, is a true and correct copy of R001564952-981 at 960.

251. Exhibit 249, attached hereto, is a true and correct copy of R001572230.

252. Exhibit 250, attached hereto, is a true and correct copy of R004792356.

253. Exhibit 251, attached hereto, is a true and correct copy of R004961456.

254. Exhibit 252, attached hereto, is a true and correct copy of R005310871.

255. Exhibit 253, attached hereto, is a true and correct copy of R005312429-2430.

256. Exhibit 254, attached hereto, is a true and correct copy of R005312436.

257. Exhibit 255, attached hereto, is a true and correct copy of R005312471.
258. Exhibit 256, attached hereto, is a true and correct copy of R005312683-774.
259. Exhibit 257, attached hereto, is a true and correct copy of R008890740-755.
260. Exhibit 258, attached hereto, is a true and correct copy of R-10-002641295.
261. Exhibit 259, attached hereto, is a true and correct copy of R11-000165902.
262. Exhibit 260, attached hereto, is a true and correct copy of R11-000636121-129.
263. Exhibit 261, attached hereto, is a true and correct copy of Rawn BIOCHEMISTRY (1989) at 106).
264. Exhibit 262, attached hereto, is a true and correct copy of Recny *et al.*, "Structural Characterization of Natural Human Urinary and Recombinant DNA-derived Erythropoietin," *J. Biol. Chem.*, 262(35) 17156-17163 (1987) at 17161.
265. Exhibit 263, attached hereto, is a true and correct copy of Roberts et al. (2002) at 462, 474.
266. Exhibit 264, attached hereto, is a true and correct copy of Schneider, Homodimerization, 1997;.
267. Exhibit 265, attached hereto, is a true and correct copy of Stewart (1959).
268. Exhibit 266, attached hereto, is a true and correct copy of Storrington et al., (1998) 100: 79-89.
269. Exhibit 267, attached hereto, is a true and correct copy of Strickland Tr. (3/9/07).
270. Exhibit 268, attached hereto, is a true and correct copy of Stryer (1988) at 4.
271. Exhibit 269 is intentionally omitted.
272. Exhibit 270, attached hereto, is a true and correct copy of Syed (1998) at 515.
273. Exhibit 271 is intentionally omitted.
274. Exhibit 272, attached hereto, is a true and correct copy of Torchilin 4/6/07 Expert Report ¶¶ 61, 86-88, 110.
275. Exhibit 273, attached hereto, is a true and correct copy of Torchilin 6/1/07 Expert Report ¶¶ 14, 30, 41, 51).
276. Exhibit 274, attached hereto, is a true and correct copy of Torchilin Dep. Tr. 06/18/07 at .

277. Exhibit 275, attached hereto, is a true and correct copy of U.S.S.N. 06/866,459.
278. Exhibit 276, attached hereto, is a true and correct copy of U.S.S.N. 07/632,070, Paper No. 15, dated December 2, 1991, p.13.
279. Exhibit 277, attached hereto, is a true and correct copy of U.S.S.N. 07/983,620, Paper No. 27, dated August 13, 1996, p. 8.
280. Exhibit 278, attached hereto, is a true and correct copy of U.S.S.N. 08/413,803, Paper No. 12, dated December 10, 1996, p. 14.
281. Exhibit 279, attached hereto, is a true and correct copy of U.S.S.N. 08/479,892, "Brief for Party Elliott" dated February 11, 2004.
282. Exhibit 280, attached hereto, is a true and correct copy of USSN 06/866,459, Paper No. 5, dated 8/3/87, pp. 4-7, 9, 10.
283. Exhibit 281 is intentionally omitted.
284. Exhibit 282, attached hereto, is a true and correct copy of Varki I at para. 86, 89, 92.
285. Exhibit 283, attached hereto, is a true and correct copy of Veronese (1985) at 142.
286. Exhibit 284, attached hereto, is a true and correct copy of Veronese et al. (1983) at 757.
287. Exhibit 285, attached hereto, is a true and correct copy of ITC-R-BLA-00004026.
288. Exhibit 286, attached hereto, Bailon & Berthold, "Polyethylene glycol-conjugated pharmaceutical proteins," PSTT 1(8): 352-356 (1998).
289. Exhibit 287, attached hereto, is a true and correct copy of Meister (ed). Biochemistry of the Amino Acids Volume 1.
290. Exhibit 288, attached hereto, is a true and correct copy of CKD Best Practice September/October 2004.
291. Exhibit 289, attached hereto, is a true and correct copy of Morgan Stanley Equity Research -AMGEN: Some Setbacks For Competitors In EU, February 23, 2006.
292. Exhibit 290, attached hereto, is a true and correct copy of Pollack, A., "Rivals Laying Siege to Amgen's Near Monopoly in Anemia Drugs," The New York Times, Dec. 23, 2005.
293. Exhibit 291, attached hereto, is a true and correct copy of Memo in Support of Roche's Motion for Summary Judgment of Non-Infringement of Claim 1 of Patent No. 5,955,422.

294. Exhibit 292, attached hereto, is a true and correct copy of Memo in Support of Roche's Motion for Summary Judgment of Non-Infringement that Claims of the '933 Are Invalid for Indefiniteness and Lack of Written Description.

295. Exhibit 293, attached hereto, is a true and correct copy of Torchilin II expert report ¶ 66.

296. Exhibit 294, attached hereto, is a true and correct copy of the Widness and Veng-Pedersen Report.

297. Exhibit 295, attached hereto, is a true and correct copy of the Supplemental Expert Report of Harvey F. Lodish

Dated: June 29, 2007
Boston, Massachusetts

/s/ Keith E. Toms
Keith E. Toms
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, Massachusetts 02110
Tel. (617) 443-9292

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