Case 1:05-cv-12237-WGY

Filed 07/05/2007

## UNITED STATES DISTRICT COURT **DISTRICT OF MASSACHUSETTS**

AMGEN INC., Plaintiff,		
VS.	)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD;	)	CIVIL 71C1101(110 03 CV 12237 WG1
ROCHE DIAGNOSTICS GmbH; and	)	
HOFFMANN-LA ROCHE INC.	)	
Defendants.	) )	

## NOTICE OF FILING WITH CLERK'S OFFICE OF EXHIBITS TO DECLARATION OF KRISTA M. RYCROFT IN SUPPORT OF ROCHE'S OPPOSITION TO PLAINTIFF AMGEN INC.'S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

Pursuant to CMF/ECF Administrative Procedures Rule M(6) notice is hereby given that the exhibits listed below have been manually filed with the Court and are available in paper form only. The original documents are maintained in the case file in the Clerk's Office

only. The original documents are maintained in the case the in the Cierk's Office.		
Exhibit 1	[submitted for in camera review]	
Exhibit 2	U.S. Patent No. 5,441,868.	
Exhibit 3	Protest by Dr. Lai in the '178 File History (Paper 31), dated July 23, 1993. (AM-ITC 00941255-61 (attachments excluded)).	
Exhibit 4	Office Action in the '178 File History (Paper 34), mailed on December 29, 1993. (AM-ITC 00941410-15).	
Exhibit 5	U.S. Patent No. 5,547,933.	
Exhibit 6	Miyake <i>et al.</i> , "Purification of Human Erythropoietin," <i>J. Biol. Chem.</i> , Vol. 252, No. 15, pp. 5558-64 (Aug. 1977). (AM-ITC 00987639-49).	
Exhibit 7	Rebuttal Expert Report of Stephen Kunin, dated May 11, 2007.	
Exhibit 8	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).	

- Exhibit 9 Preliminary Amendment in the '179 File History (Paper 7), dated October 23, 1987. (AM-ITC 00953195-203).
- Exhibit 10 Applicant's Second Preliminary Amendment in the '179 File History (Paper 8), dated May 24, 1988. (AM-ITC 00953204-25).
- Exhibit 11 Examiner Interview Summary Record in the '179 File History (Paper 30) dated November 13, 1993. (AM-ITC 00953602-03).
- Exhibit 12 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).
- Exhibit 13 Information Disclosure Statement in the '179 File History (Paper 44). (AM-ITC 00953710-11).
- Exhibit 14 Preliminary Amendment in the '381 File History (Paper 4), dated June 6, 1995. (AM-ITC 00898298-301).
- Exhibit 15 IDS filed in the '381 File History (Paper 6), dated January 3, 1996. (AM-ITC 00898307-33).
- Exhibit 16 Interview Summary in the '381 File History (Paper 7), dated December 11, 1996. (AM-ITC 00898334-37).
- Exhibit 17 Preliminary Amendment in the '369 File History (Paper 5), dated June 6, 1995. (AM-ITC 00898621-24).
- Exhibit 18 Second Preliminary Amendment in the '369 File History (Paper 8), dated December 20, 1996. (AM-ITC 00898654-63).
- Exhibit 19 Disclosure Statement and accompanying PTO-1449 in the '369 File History (Paper 6), dated January 3, 1996. (AM-ITC 00898625-51).
- Exhibit 20 Information Disclosure Statement in the '369 File History (Paper 9), dated December 20, 1996. (AM-ITC 00898691-92).
- Exhibit 21 Associate Power of Attorney in the '073 File History (Paper 11), dated December 30, 1992. (AM-ITC 00899119-21).
- Exhibit 22 Examiner Interview Summary Record in the '369 File History (Paper 7), dated December 11, 1996. (AM-ITC 00898652-53).
- Exhibit 23 Preliminary Amendment in the '178 File History (Paper 3), dated October 23, 1987. (AM-ITC 00941081-88).
- Exhibit 24 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).

Exhibit 25	communication from Examiner Schain to Mr. Borun in the '178 File History (Paper 21). (AM-ITC 00941224-27).
Exhibit 26	Examiner Interview Summary Record in the '178 File History (Paper 32), dated November 18, 1993. (AM-ITC 00941406-07).
Exhibit 27	Examiner Interview Summary Record in the '178 File History (Paper 33), dated November 22, 1993. (AM-ITC 00941408-409).
Exhibit 28	Notice of Change of Address in the '178 File History (Paper 30). (AM-ITC 00941253-54).
Exhibit 29	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).
Exhibit 30	Interview Summary from the '556 File History (Paper 4), dated December 11, 1996. (AM-ITC 00868071-73).
Exhibit 31	Information Disclosure Statement and accompanying PTO-1449 in the '556 File History (Paper 7), dated December 20, 1996. (AM-ITC 00868126-55).
Exhibit 32	[submitted for in camera review]
Exhibit 33	[submitted for in camera review]
Exhibit 34	[submitted for in camera review]
Exhibit 35	[submitted for in camera review]
Exhibit 36	Associate Power of Attorney in the '179 File History (Paper 2), dated February 9, 1988. (AM-ITC 00953131-33).
Exhibit 37	Examiner Interview Summary Record in the '179 File History (Paper 10) dated September 14, 1988. (AM-ITC 00953232-34).
Exhibit 38	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).
Exhibit 39	Petition for Access filed in the '179 File History (Paper 12), dated September 27, 1988. (AM-ITC 00953250-56).

May 1, 1989. (AM-ITC 00953313-17).

4), dated July 20, 1988. (AM-ITC 00941101).

Exhibit 40

Exhibit 41

Request for Withdrawal of Suspension in the '179 File History (Paper 20), dated

Examiner Interview Summary Record in the '178 File History (attached to Paper

Exhibit 42	Examiner Interview Summary Record in the '178 File History (Paper 8) dated January 26, 1989. (AM-ITC 00941145-46).
Exhibit 43	Examiner Interview Summary Record in the '178 File History (Paper 14) dated June 22, 1989. (AM-ITC 00941184-85).
Exhibit 44	Examiner Interview Summary Record in the '178 File History (Paper 17), dated December 20, 1989. (AM-ITC 00941204-05).
Exhibit 45	Power of Attorney in the '178 File History (Paper 24), dated February 22, 1990. (AM-ITC 00941241-42).
Exhibit 46	March 29, 2007 deposition transcript of Stuart Watt.
Exhibit 47	September 7, 2000 trial testimony of Stuart Watt.
Exhibit 48	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).
Exhibit 49	Examiner Interview Summary Record in the '369 File History (Paper 11), dated May 6, 1997. (AM-ITC 00898727-28).
Exhibit 50	Examiner Interview Summary Record in the '197 File History (Paper 24), dated March 1, 1995. (AM-ITC 00899176-77).
Exhibit 51	Examiner Interview Summary Record in the '197 File History (Paper 32), dated April 21, 1999. (AM-ITC 00899440-41).
Exhibit 52	Terminal Disclaimer in the '197 File History (Paper 35), dated April 26, 1999. (AM-ITC 00899686-88).
Exhibit 53	Examiner Interview Summary Record in the '774 File History (Paper 46), dated October 18, 1995. (AM-ITC 00941538-39).
Exhibit 54	[submitted for in camera review]
Exhibit 55	[submitted for in camera review]
Exhibit 56	Declaration of Fu-Kuen Lin, submitted in Interference No. 102,334, dated March 18, 1991. (AM-ITC 00295809-16).
Exhibit 57	[submitted for in camera review]
Exhibit 58	[submitted for in camera review]
Exhibit 59	[submitted for in camera review]

- Exhibit 60 Declaration of Thomas Strickland Pursuant to 37 C.F.R. §1.132, dated November 30, 1988. (AM-ITC 00941119-44).
- Exhibit 61 U.S. Patent No. 4,667,016 (Lai et al.).
- Exhibit 62 U.S. Patent No. 4,703,008.
- Exhibit 63 Amgen v. ITC, 902 F.3d 1532 (Fed. Cir. 1990).
- Exhibit 64 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).
- Exhibit 65 CHARLES W. RIVISE & A.D. CAESAR, INTERFERENCE LAW AND PRACTICE, Vol. I § 6 (Michie Co., 1940).
- Exhibit 66 [submitted for *in camera* review]
- Exhibit 67 Associate Power of Attorney filed in the '179 File History (Paper 2) on February 9, 1988. (AM-ITC 00953131-33).
- Exhibit 68 [submitted for *in camera* review]
- Exhibit 69 MPEP § 2002.03(b) (5th ed. Rev. 3, May 1986).
- Exhibit 70 Fritsch v. Lin, 21 U.S.P.Q.2d 1737 (Bd. Pat. App. & Interf. 1992).
- Exhibit 71 MPEP § 2001.05 (5<sup>th</sup> ed. Rev. 3, May 1986).
- Exhibit 72 Statement of Grounds submitted on October 8, 1992 by Amgen in the EP 411 678 Opposition Proceedings.
- Exhibit 73 MPEP § 804 (8<sup>th</sup> ed., Rev. 5, Aug. 2006).
- Exhibit 74 Notice of Allowability in the '179 File History (Paper 46), mailed on February 6, 1995. (AM-ITC 00953708).
- Exhibit 75 Amendment Under Rule 116 in the '178 File History (Paper 19), dated January 10, 1990. (AM-ITC 00941211-20).
- Exhibit 76 Office Action in the '179 File History (Paper 29), mailed on September 1, 1993. (AM-ITC 00953590-601).
- Exhibit 77 Office Action in the '179 File History (Paper 34), mailed on February 15, 1994. (AM-ITC 00953649-56).
- Exhibit 78 Miyake *et al*, "Purification of Human Erythropoietin" (1977). (AM-ITC 00941138-44).

- Exhibit 80 U.S. Patent No. 5,621,080.
- Exhibit 81 Preliminary Amendment in the '874 File History (Paper 37), dated June 13, 1994. (AM-ITC 00941451-54).
- Exhibit 82 [submitted for *in camera* review]
- Exhibit 83 [submitted for *in camera* review]
- Exhibit 84 Request for Withdrawal of Suspension in the '179 File History, dated May 1, 1989. (AM-ITC 00900823-26).
- Exhibit 85 Amendment Under Rule 116 in the '178 File History (Paper 11), dated June 2, 1989. (AM-ITC 00997385-92).
- Exhibit 86 Amendment Under Rule 116 in the '178 File History (Paper 11), dated June 2, 1989. (AM-ITC 00941164-72).
- Exhibit 87 "Lin EPO Patents." (AM-ITC 00906488).
- Exhibit 88 MPEP § 609.02 (8<sup>th</sup> ed. Rev. 5, Aug. 2006).
- Exhibit 89 communication from the Examiner in the '179 File History (Paper 16), dated December 2, 1988. (AM-ITC 00953282-83).
- Exhibit 90 Request for Withdrawal of Suspension in the '179 File History (Paper 20), dated May 1, 1989. (AM-ITC 00953314-524).
- Exhibit 91 Declaration of Interference in the '179 File History (Paper 21), mailed on May 8, 1989. (AM-ITC 00953525-28).
- Exhibit 92 Interference Digest in the '179 File History (Paper 22). (AM-ITC 00953529-30).
- Exhibit 93 Search Notes from the '422 Patent File History. (AM-ITC 00899764).
- Exhibit 94 Second Preliminary Amendment and Remarks in the '774 File History (Paper 50), dated December 20, 1995. (AM-ITC 00941543-51).
- Exhibit 95 '178 application. (AM-ITC 00940939-1074).
- Exhibit 96 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).
- Exhibit 97 Amendment in the '178 File History (Paper 15), dated July 11, 1989. (AM-ITC 00941187-97).

Exhibit 98	Examiner Interview Summary Record in the '178 File History (Paper 18), dated
	December 20, 1989. (AM-ITC 00941206-10).

- Exhibit 99 Office Action in the '178 File History (Paper 4), mailed on June 2, 1988. (AM-ITC 00941089-100).
- Exhibit 100 Egrie *et al.*, Characterization of Recombinant Monkey and Human Erythropoietin, *Proc. Clin. Biol. Res.* 1985, 191:339-50.
- Exhibit 101 [submitted for in camera review]
- Exhibit 102 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).
- Exhibit 103 [submitted for *in camera* review]
- Exhibit 104 [submitted for in camera review]
- Exhibit 105 Trial testimony of Michael Borun from September 6, 2000.
- Exhibit 106 Trial testimony of Michael Borun from February 5, 2002.
- Exhibit 107 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).
- Exhibit 108 Trial transcript from Amgen v. TKT
- Exhibit 109 Office Action in the '178 File History (Paper 9), mailed on February 10, 1989. (AM-ITC 00941147-60).
- Exhibit 110 Office Action in the '178 File History (Paper 13), mailed on June 20, 1989. (AM-ITC 00941175-83).
- Exhibit 111 WO 86/03520.
- Exhibit 105 Preliminary Amendment in the '874 File History (Paper 45), dated June 7, 1995. (AM-ITC 00941535-57)
- Exhibit 113 MPEP § 704.01 (5<sup>th</sup> ed., Rev. 6, Oct. 1987).
- Exhibit 114 Notice of Allowability in the '774 File History (Paper 52). (AM-ITC 00941561-66).
- Exhibit 115 June 6, 1997 Notice of Allowability in the '556 File History (Paper 9). (AM-ITC 00868157-61).
- Exhibit 116 Declaration of Interference in the '178 File History (Paper 22). (AM-ITC 00941228-35).

- Exhibit 117 Interference Digest in the '178 File History (Paper 23). (AM-ITC 00941236-37).
- Exhibit 118 [submitted for *in camera* review]
- Exhibit 119 [submitted for *in camera* review]
- Exhibit 120 October 5, 1998 PTO Initiative, "Changes to Implement the Patent Business Goals," Vol. 63, No. 192, pp. 53498-530.
- Exhibit 121 June 27, 2007 deposition transcript of Stephen Kunin.
- Exhibit 122 Eschbach *et al.*, Correction of the Anemia of End-Stage Renal Disease with Recombinant Human Erythropoietin, *NEJM* 316:73-78 (1987) (Egrie, co-author).
- Exhibit 123 Vapnek *et al.*, "Comparative Studies of Natural and Recombinant Erythropoietin," *Banbury Reports* 29: *Therapeutic Peptides and Proteins*, 241-56 (1988). (AM-ITC 00580141-56).
- Exhibit 124 April 15, 1991 deposition transcript of Joan Egrie.
- Exhibit 125 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).
- Exhibit 126 Declaration of Thomas Heckler, dated May 19, 1992. (AM-ITC 00311601-18).
- Exhibit 127 Declaration of Eugene Goldwasser, dated January 23, 1993. (AM-ITC 01009089-129).
- Exhibit 128 [submitted for in camera review]
- Exhibit 129 Terminal Disclaimer in the '381 File History (Paper 8), dated December 20, 1996. (AM-ITC 00898338-41).
- Exhibit 130 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.
- Exhibit 131 March 27, 2007 Letter from Ross to Rycroft.
- Exhibit 132 [submitted for *in camera* review]
- Exhibit 133 Physician's Desk Reference (44<sup>th</sup> ed. 1990) at 616.
- Exhibit 134 Amgen's June 1994 Product Label for Epogen<sup>®</sup>. (AM-ITC 00601553-60).
- Exhibit 135 March 9, 2007 Product Labels for Epogen<sup>®</sup> and Procrit<sup>®</sup> available at <a href="http://www.accessdata.fda.gov">http://www.accessdata.fda.gov</a>.

- Exhibit 136 [submitted for *in camera* review]
- Exhibit 137 Office Action in the '298 File History (Paper 17), dated June 18, 1987. (R008892042-48).
- Exhibit 138 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).
- Exhibit 139 Examiner Interview Summary Record in the '298 File History (Paper 21), dated July 30, 1987. (R008892076).
- Exhibit 140 [submitted for in camera review]
- Exhibit 141 [submitted for *in camera* review]
- Exhibit 142 [submitted for *in camera* review]
- Exhibit 143 [submitted for *in camera* review]
- Exhibit 144 [submitted for *in camera* review]
- Exhibit 145 [submitted for *in camera* review]
- Exhibit 146 [submitted for *in camera* review]
- Exhibit 147 [submitted for *in camera* review]
- Exhibit 148 [submitted for *in camera* review]
- Exhibit 149 Gaylis *et al.*, "In Vitro Models of Human Testicular Germ-Cell Tumors", *World J. Urol.*, 2:2-5 (1984).
- Exhibit 150 Drs. Ascensao, Gaylis, Fraley, Bronson and Zanjani, entitled "Inducible Production of Erythropoietin By A Human Yolk Sac Tumor Line." (AM-ITC 00057739).
- Exhibit 151 [submitted for *in camera* review]
- Exhibit 152 Intentionally left blank.
- Exhibit 153 Ascensao *et al.*, "Erythropoietin Production by a Human Testicular Germ Cell Line", *Blood* 62(5):1132-34 (1983).
- Exhibit 154 [submitted for *in camera* review]
- Exhibit 155 U.S. Patent No. 5,441,868.
- Exhibit 156 EP 0 093 619.

- Exhibit 157 February 21, 1984 Genentech Press Release, accessible at <a href="http://www.gene.com/gene/news/press-releases">http://www.gene.com/gene/news/press-releases</a>.
- Exhibit 158 November 13, 1987 FDA Press Release, accessible at <a href="http://www.fda.gov/bbs/topics/NEWS/NEW00191.html">http://www.fda.gov/bbs/topics/NEWS/NEW00191.html</a>.
- Exhibit 159 Office Action in the '179 File History (Paper 9), mailed on August 3, 1988. (AM-ITC 00953226-31)
- Exhibit 160 U.S. Patent No. 4,766,075.
- Exhibit 161 Information Disclosure Statement in the '179 File History (Paper 15), dated September 26, 1988. (AM-ITC 00953279-81).
- Exhibit 162 Notice of Allowability in the '179 File History. (AM-ITC 00953308).
- Exhibit 163 Notice of Allowability with an illegible date in the '381 File History (Paper 12). (AM-ITC 00898389-90).
- Exhibit 164 U.S. Patent No. 4,966,843 (McCormick et al.).
- Exhibit 165 U.S. Serial No. 438,991.
- Exhibit 166 September 6, 1984 Declaration Under 37 C.F.R. § 1.131 in the '843 File History.
- Exhibit 167 MPEP § 706.02 (5<sup>th</sup> ed., Rev. 6, Oct. 1987).
- Exhibit 168 [submitted for *in camera* review]
- Exhibit 169 [submitted for *in camera* review]
- Exhibit 170 U.S. Patent No. 5,756,349.
- Exhibit 171 [submitted for *in camera* review]
- Exhibit 172 [submitted for *in camera* review]
- Exhibit 173 [submitted for *in camera* review]
- Exhibit 174 [submitted for *in camera* review]
- Exhibit 175 MPEP § 2004 (5<sup>th</sup> ed. Rev. 3, May 1986).
- Exhibit 176 MPEP § 2004 (8<sup>th</sup> ed. Rev. 5, Aug. 2006).
- Exhibit 177 [submitted for in camera review]
- Exhibit 178 [submitted for *in camera* review]

- Exhibit 179 Amgen's Amended Complaint against Hoechst Marion Roussel, Inc., dated October 7, 1999. (AM-ITC 00823572-90).
- Exhibit 180 MPEP § 2001.06(b) (5th ed. Rev. 3, May 1986).
- Exhibit 181 MPEP § 2001.01 (8th ed. Rev. 5, Aug. 2006).
- Exhibit 182 U.S. Gen. Accounting Office, GAO-RCED-89-120BR, Biotechnology, Backlog of Patent Applications, at 20 (1989).
- Exhibit 183 Examiner Interview Summary Record in the '178 File History (Paper 51), dated March 14, 1996. (AM-ITC 00941552-53).
- Exhibit 184 U.S. Patent No. 5,955,422.
- Exhibit 185 Preliminary Amendment in the '741 File History (Paper 2), dated November 6, 1990. (AM-ITC 00899075-87).
- Exhibit 186 [submitted for *in camera* review]
- Exhibit 187 Amendment Under Rule 1.116 in the '197 File History (Paper 18), dated December 20, 1993. (AM-ITC 00899150-54).
- Exhibit 188 Examiner Interview Summary Record in the '197 File History (Paper 17), dated November 23, 1993. (AM-ITC 00899148-49).
- Exhibit 189 Garcia, JF, and JC Schooley, "Disassociation of Erythropoietin from Erythropoietin-Antierythropoietin Complex," *Proc. Soc. Biol. Med.* 138:213-215 (1971).
- Exhibit 190 [submitted for *in camera* review]
- Exhibit 191 [submitted for in camera review]
- Exhibit 192 [submitted for *in camera* review]
- Exhibit 193 [submitted for *in camera* review]
- Exhibit 194 [submitted for *in camera* review]
- Exhibit 195 Information Disclosure Statement and accompanying PTO-1449 in the '197 File History (Paper 34), dated April 28, 1999. (AM-ITC 00899477-515).
- Exhibit 196 Office Action in the '197 File History (Paper 20), mailed on June 1, 1994. (AM-ITC 00899157-61).
- Exhibit 197 Request for Reconsideration in the '197 File History (Paper 23), dated December 1, 1994. (AM-ITC 00899169-75).

- Exhibit 198 [submitted for *in camera* review]
- Exhibit 199 [submitted for *in camera* review]
- Exhibit 200 Amendment in the '197 File History (Paper 33), dated April 28, 1999. (AM-ITC 00899469-75).
- Exhibit 201 [submitted for *in camera* review]
- Exhibit 202 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).
- Exhibit 203 Yalow, R.S. and Berson, S.A., "Immunoassay of Endogenous Plamsa Insulin in Man," *J. Clin. Invest.* 39, 1157-75. (1960).
- Exhibit 204 Yalow, R. "Radioimmunoassay: A Probe for Fine Structure of Biological Systems", Nobel Lecture, pp. 447-68 (12/8/77).
- Exhibit 205 Exhibit 205 is intentionally left blank.
- Exhibit 206 Garcia, J. F. "Assays for Erythropoietin" *in* Kidney Hormones (1977) vol. 2, pp. 7-35.
- Exhibit 207 Clemons, G.K. (1988) Comparison of Radioimmunoassay and Bioassays of Erythropoietin, *in* REGULATION OF ERYTHROPOIESIS: SYMPOSIUM ON ERYTHROPOIESIS 363-374.
- Exhibit 208 Garcia, J.F. "Radioimmunoassay of Human Plasma Erythropoietin" *in*: Regulation of Erythropoiesis: 1<sup>st</sup> International Conference on Hematopoiesis (1971), pp. 132-153.
- Exhibit 209 U.S. Patent No. 4,254,095.
- Exhibit 210 Sherwood and Goldwasser, "A radioimmunoassay for erythropoietin," *Blood* (1979) 54(4), pp. 885-893 (1979).
- Exhibit 211 Garcia et al, "Radioimmunoassay of erythropoietin," *Blood Cells* (1979) 5(3), PP. 405-419.
- Exhibit 212 Zaroulis et al., "A microimunnoflourescent assay to detect human granulocyte antigens & antibodies." *Am. J. Hematol.* (1981) 10, pp. 65-73.
- Exhibit 213 Rege et al., "A radioimmunoassay for erythropoietin: serum levels in normal human subjects and patients with hematopoietic disorders," *J. Lab. Clin. Med.* (1982) 100(6), pp. 829-843.

- Exhibit 214 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.
- Exhibit 215 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.
- Exhibit 216 Goldwasser, J. Biol. Chem., vol. 249, pp. 4202-06 (1974).
- Exhibit 217 White et al., "Studies in erythropoietin" *Recent Prog. Horm. Res.*, 16:219, 1960.
- Exhibit 218 Goldwasser, "Studies on Erythropoiesis," J. Lab. Clin. Med. 50(4):534-42 (1958).
- Exhibit 219 Cotes and Bangham, "The international reference preparation of erythropoietin," (1966) *Bull. World Health Org* 35(5), 751-760.
- Exhibit 220 Annable et al., "The Second International Reference Preparation of Erythropoietin, Human, Urinary, For Bioassay." *Bull. World Health Org.* (1972), 47(1), pp. 99-112
- Exhibit 221 [submitted for *in camera* review]
- Exhibit 222 Storring and Gaines Das, "The International standard for recombinant DNA-derived erythropoietin," *J. of Endocrinology*, Vol. 134, pp. 459-84 (1992).
- Exhibit 223 June 21-22, 1982 Report of the Erythropoietin Assay Workshop. (UCH00002512-17).
- Exhibit 224 [submitted for *in camera* review]
- Exhibit 225 [submitted for *in camera* review]
- Exhibit 226 [submitted for *in camera* review]
- Exhibit 227 MPEP § 2001.04 (5th ed. Rev. 14, 1992).
- Exhibit 228 MPEP § 2363.02 (5<sup>th</sup> ed. Rev. 13, Nov. 1989).
- Exhibit 229 MPEP § 2363.02 (8<sup>th</sup> ed., Aug. 2001).
- Exhibit 230 MPEP § 2301 (8<sup>th</sup> ed. Rev. 5, Aug. 2006).
- Exhibit 231 MPEP § 706 (5<sup>th</sup> ed. Rev. 6, Oct. 1987).
- Exhibit 232 MPEP § 706 (8<sup>th</sup> ed. Rev. 5, Aug. 2006).
- Exhibit 233 MPEP § 708.02 (5<sup>th</sup> ed. Rev 6, Oct. 1987).

Exhibit 234	MPEP § 708.02 (8 <sup>th</sup> ed. Rev. 5, Aug. 2006).
Exhibit 235	U.S. Patent No. 4,879,272.
Exhibit 236	"Guidelines for Reexamination Of Cases In View of In Re Portola Packaging, Inc." 1223 OG 124.
Exhibit 237	Office Action in the '874 File History (Paper 38), mailed on August 16, 1994 (AM-ITC 00941455-66).
Exhibit 238	Office Action in the '874 File History (Paper 43), mailed on May 17, 1995 (AM-ITC 00941522-29).
Exhibit 239	Declaration of interference in the '741 File History (Paper 8), mailed on November 20, 1992 (AM-ITC 00899104-07).
Exhibit 240	Interference Digest in the '741 File History (Paper 9) (AM-ITC 00899108-09).
Exhibit 241	Declaration of interference in the '741 File History (Paper 8), mailed on November 20, 1992. (AM-ITC 00899104-07).
Exhibit 242	Portions of U.S. Patent No. 5,618,698.
Exhibit 243	[submitted for in camera review]
Exhibit 244	[submitted for in camera review]
Exhibit 245	[submitted for in camera review]
Exhibit 246	[submitted for in camera review]
Exhibit 247	Office Action in the '178 File History (Paper 16), mailed on September 18, 1989. (AM-ITC 00941198-203).
Exhibit 248	Decision on Petition to Make Special in the '179 File History (Paper 5). (AM-ITC 00953191-92).
Exhibit 249	Communication from Examiner Schain in the '178 File History (Paper 21). (AM-ITC 00941224-27).

Dated: July 5, 2007

Boston, Massachusetts

Respectfully submitted,

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

By their attorneys,

/s/ Keith E. Toms
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