Amgen Inc. v. F. Hoffmann-LaRoche LTD et al

Doc. 1217 Att. 1

EXHIBIT A

LIST OF EXHIBITS

ANCIENT DOCUMENTS

(CATEGORY A)

Tab	Ex. #	Date	Description	Relevance
1.	DOK	00/00/1974	Goldwasser, et al., "On the mechanism of erythropoietin-induced differentiation: XIII. The role of sialic acid in erythropoietin action," J. Biol. Chem. 249(13):4202-6 (1974)	Prior art
2.	DRF	00/00/1981	Korninger, C., et al., "Turnover of Human Extrinsic Plasminogen Activator in Rabbits," <i>Thromb. Haemostasis</i> 46, 658-661 (1981)	Prior art
3.	DSB	07/00/1981	Lodish, "Post-Translational Modification of Proteins," <i>Enzyme Microb Technol</i> . 1981 Jul; 3(3):177-280, at 186	Prior art
4.	DPI	00/00/1982	Gutterman, et al., "Recombinant Leukocyte A Interferon: Pharmacokinetics, Single Dose Tolerance, and Biological Effects in Cancer Patients," Annals of Internal Medicine 96:549-566 (1982)	Prior art
5.	DQQ	00/00/1983	Kelker <i>et al.</i> , "Effects of Glycosidase Treatment on the Physiochemical Properties and Biological Activity of Human Interferon-γ" <i>J. Biol. Chem.</i> 258:8010-13 (1983)	Prior art

Tab	Ex. #	Date	Description	Relevance
6.	DRC	00/00/1983	Konrad, M. <i>et al.</i> , "Applications of genetic engineering to the pharmaceutical industry," <i>Ann N Y Acad Sci.</i> 413:12-22 (1983)	Prior art
7.	DIU	00/00/1984	Colby, C.B., <i>et al.</i> , "Immunologic differentiation between <i>E. coli</i> and CHO cell-derived recombinant and natural human beta-interferons," <i>J. Immunol.</i> 133(6):3091-5 (1984)	Prior art
8.	DNY	00/00/1984	Gaylis, F.D., <i>et al.</i> , " <i>In vitro</i> models of human testicular germ-cell tumors." <i>World J. of Urol.</i> 2:2-5, 5 (1984)	Prior art
9.	CXJ	04/00/1984	Hagiwara, et al., "Erythropoietin production in a primary culture of human renal carcinoma cells maintained in nude mice." <i>Blood</i> 63(4):828-835 (1984)	Prior art
10.	DAH	00/00/1984	Little, S.P., <i>et al.</i> , "Functional Properties of Carbohydrate Depleted Tissue Plasminogen Activator," <i>Biochemistry</i> 23, 6191-6195 (1984)	Prior art
11.	DCI	00/00/1984	Nilsson, T., <i>et al.</i> , " <i>In vivo</i> metabolism of human tissue-type plasm" <i>Scand. J. Haematol.</i> 33, 49-53 (1984)	Prior art
12.	GWV	07/18/1985	Kopito et al., "Primary structure and transmembrane orientation of the murine anion exchange protein", Nature (1985) 316: pp. 234-238	Reflects the state of the prior art as of 1983-1984.

Tab	Ex. #	Date	Description	Relevance
13.	DCD	00/00/1985	Mueckler et al., "Sequence and structure of a human glucose transporter," <i>Science</i> , Vol. 229, pp. 941-5	Reflects the state of the prior art as of 1983-1984.
14.	GWW	02/25/1985	Spiess et al., "Sequence of Human Asialoglycoprotein Receptor cDNA", Journal of Bio Chem., 260: pp. 1979-1982	Reflects the state of the prior art as of 1983-1984.

Tab	Ex. #	Date	Description	Relevance
15.	ABZ	10/21/1985	Paper 16, "Amendment," from certified file history of U.S. Patent No. 4,766,075	Excerpt from certified file history of patent previously put in evidence by Roche as invalidating prior art (Exhibit 2030)
				Reflects the state of the prior art as of 1983-1984:
				("It would have been appreciated by those skilled in the art at the time this invention was made [1982-83] that the expression of human t-PA in transformed cells would be fraught with many potential difficulties. The art of recombinant DNA technology appears to be deceptively straightforward but is inherently unpredictable.")
				("Thus, it would certainly have been unpredictable before the fact that one could obtain by recombinant DNA technology a biologically active protein such as the one forming the basis of the present invention.")
				See Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision, Inc., 1998 U.S. Dist. LEXIS, No. 94-cv-6296, at *29 (S.D.N.Y. Mar. 26, 1998) (noting that statements in other prosecution histories "may help inform a Court's understanding of the state of the art at the time")

Tab	Ex. #	Date	Description	Relevance
16.	CUE	00/00/1986	Erslev, A.J., and Caro, J., "Physiologic and molecular biology of erythropoietin," <i>Med. Oncol. Tumor. Pharmacother.</i> 3(3-4):159-64 (1986)	Reflects the state of the prior art as of 1983-1984: ("The exact cellular source for erythropoietin production in the kidney is still unknown.")
17.	DCQ	00/00/1986	Opdenakker et al., "Influence of Carbohydrate Side Chains on Activity of Tissue-Type Plasminogen Activator," Proc. Soc. Experimental Biology and Medicine 182:248-257 (1986)	Reflects the state of the prior art as of 1983-1984: ("The biological significance of the carbohydrate moiety has until now not been documented. Here we describe experiments which demonstrate that alterations in the carbohydrate can affect <i>in vitro</i> enzymatic activity of tissue-type plasminogen activator.")
18.	DHA	00/00/1986	Vehar et al., "Characterization studies of human tissue-type plasminogen activator produced by recombinant DNA technology." Cold Spring Harbor Symp. On Quant. Biol. 51:551-562 (1986)	Reflects the state of the prior art as of 1983-1984 ("Although preliminary studies on t-PA produced by a melanoma cell line were promising (Weimar et al. 1981; Van de Werf et al. 1984), it was not clear whether sufficient material could be produced to make a sufficient fibrinolytic product at a cost-effective price using the natural sources (Collen et al. 1982). The application of recombinant DNA techniques to solve this problem led initially to the expression of the protein in bacteria (Pennica et al. 1983).")

Tab	Ex. #	Date	Description	Relevance
19.	CVS	07/00/1983	Fisher. Control of erythropoietin production. Proc Soc Exp Biol. Med. 1983 Jul;173(3):289-305	Prior art
20.	DNJ	00/00/1980	Fisher. Mechanism of the anemia of chronic renal failure. Nephron. 1980; 25(3):106-11.	Prior art and objective evidence of non- obviousness as of 1983-1984.
21.	GWL	00/00/1967	Van Dyke et al., Erythropoietin Therapy in the Renoprival Patient, U.S. Atomic Energy Commission, UCRL (1967) 17481:127-132	Prior art and objective evidence of non- obviousness as of 1983-1984.
22.	DTL	08/00/1971	Nakao et al. Erythropoiesis in anephric or kidney transplanted patients. Isr. J. Med. Sci. 1971 Jul-Aug;7(7):986-90.	Prior art and objective evidence of non- obviousness as of 1983-1984.
23.	DMJ	04/15/1971	Erslev. The search for erythropoietin. N. Engl. J. Med. 1971 Apr 15;284(15):849-50	Prior art and objective evidence of non- obviousness as of 1983-1984.
24.	FJT	08/2/1984	Letter from Schmergel to Albert Einstein College of Medicine re Failure of GI to express EPO from cell line (authenticated via WYETH declaration)	Secondary considerations – failure of others. Reflects failure of Genetics Institute to clone the EPO gene using cDNA cloning technique.

LIST OF EXHIBITS

ADMISSIONS BY PARTY OPPONENT

(CATEGORY B)

Tab	Ex.#	Date	Description	Relevance
25.	AJK	11/02/2001	Roche patent, U.S. Patent No. 6,544,748 B2, "Preparation of Erythropoietin by Endogenous Gene Activation," (Assignee Roche Diagnostics GmbH)	Roche admits human EPO includes a protein having a length of both 166 amino acids and 165 amino acids. (Col. 6: 26-31.)

LIST OF EXHIBITS

PUBLIC RECORDS

(CATEGORY C)

	(CITEGORI C)					
Tab	Ex.#	Date	Description	Relevance		
26.	AHF	07/02/1996	Paper 6, "Amendment," from certified file history of U.S. Patent No. 5,869,314	Excerpt from certified file history of a patent that claims priority to a patent that was previously put in evidence by Roche as invalidating prior art (Exhibit 2030) Reflects the state of the prior art as of 1983-1984: ("As argued previously, at the time the invention was made [1982-83] it was unknown (a) what effect glycosylation differences would have on the biological activity of a protein, and (b) whether the cell type used for expression of the protein would effect the glycosylation pattern. Thus, it would not have been predictable whether such glycosylation differences would, in fact, produce intact, functionally biologically active glycoprotein.") See Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision, Inc., 1998 U.S. Dist. LEXIS, No. 94-cv-6296, at *29 (S.D.N.Y. Mar. 26, 1998) (noting that statements in other prosecution histories "may help inform a Court's understanding of the state of the art at the time")		

Tab	Ex.#	Date	Description	Relevance
Tab 27.	Ex.# AHQ	Date 11/21/1996	Paper 6, "Amendment," from certified file history of U.S. Patent No. 5,753,486	Relevance Excerpt from certified file history of a patent that claims priority to a patent that was put in evidence by Roche as invalidating prior art (Exhibit 2030) Reflects the state of the prior art as of 1983-1984: ("The applicants submit that at the time the invention was made [1982-83], and even today, it would not have been predictable whether such glycosylation differences would in fact produce intact, functionally biologically active glycoprotein.") ("These articles are powerfully instructive as to the contemporary state of the art, emphasizing the patentable difference glycosylation makes, especially in 1982 when this application was effectively filed.")
				See Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision, Inc., 1998 U.S. Dist. LEXIS, No. 94-cv-6296, at *29 (S.D.N.Y. Mar. 26, 1998) (noting that statements in other prosecution histories "may help inform a Court's understanding of the state of the art at the time")

LIST OF EXHIBITS

MARKET REPORT / COMMERCIAL PUBLICATION

(CATEGORY D)

Tab	Ex.#	Date	Description	Relevance
28.	FUP	2006	US Renal Data Service Annual Report on incidence of ESRD (2006)	Objective evidence of non-obviousness as of 1983-1984. Provides historical data about the numbers of ESRD patients in need of treatment