UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

October 2, 2007, motion allowed in part and denied in part. Where allowed, the allowance is subjected to particularized objection by Roche. Where denied, the denial is without prejudice. See particularized notations herein. Exhibits FTF and GUR, however, are not admissible. The Chugai and GI documents are not admissible for the reasons advanced by Roche notwithstanding their antiquity.
William G. Young
District Judge

PLAINTIFF AMGEN INC.'S MOTION TO ADMIT EXHIBITS INTO EVIDENCE

Plaintiff Amgen Inc. ("Amgen") respectfully moves to have certain documents set forth on the chart attached hereto as Exhibit A moved into evidence in this case.[1] The documents on the chart are divided into four categories (Categories A, B, C, and D) and for the reasons set forth below should be admitted into evidence in this matter.

Category A consists of documents that have been in existence for twenty years or more and are ancient documents. Statements in ancient documents are an exception to hearsay under Fed. R. Evid. 803(16). As ancient documents, these documents should also be deemed authentic under Fed. R. Evid 901(b)(8) without the need for any further requirement of authentication or identification. Documents Nos. 1-11 and 19-23 of these ancient documents under Category A are relevant because they are prior art references and/or constitute objective evidence of non-obviousness as of 1983-1984. The determination of whether a reference is prior art is a question

[1] Copies of the documents will be filed manually with the Court on Monday, October 1, 2007.

of law for the court. *See Typeright Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004) ("Whether a reference was published prior to the critical date, and is therefore prior art, is a question of law based on underlying fact questions"). Document Numbers 12-18 of the ancient documents are relevant because they reflect the state of the prior art. Document 24 of the ancient documents is relevant because it is secondary consideration evidence reflecting the failure of others to clone EPO. This document is authenticated as an ancient document by the "Declaration of WYETH Regarding Produced Documents", which is attached hereto as Exhibit B.

Category B, Document Number 25, consists of a patent-related document authored by defendant, Roche Diagnostics GmbH ("Roche"). This document does not constitute hearsay because it is an admission of Roche under Fed. R. Evid. 801(d)(2). Pursuant to Fed. R. Evid. 801(d)(2), this document is "being offered against a party and is (1) the party's own statement, in either an individual or a representative capacity or . . . (D) a statement by the party's agent or servant concerning a matter within the scope of the agency or employment made during the existence of the relationship." Admissions by party opponents are excluded from the category of hearsay. *See* Fed. R. Evid. 801(d)(2). Parties are not prejudiced by the admission into evidence of their own statements since the parties may take the stand and contradict the statement if they so choose. *See Globe Sav. Bank, F.S.B. v. United States*, 61 Fed. Cl. 91, 94-95 (2004), judgment entered 65 Fed. Cl. 330 (2005), *aff'd in part, rev'd in part on other grounds*, 189 Fed. Appx. 964 (Fed. Cir. 2006).

Category C, Document Numbers 26 and 27, consists of documents that are excerpts of the certified file histories of certain patents. The patent file histories contain the records of the proceedings before the patent office and therefore constitute public records of the patent office.

See Pieczenick and I.C. Technologies, Inc. v. Dyax, Corp., 226 F.Supp.2d 314, 317 (D.Mass. 2002) *quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("The claims, specifications, and file history constitute the patent's public record . . . on which the public is entitled to rely"). The documents in this category are therefore public record documents and are an exception to hearsay under Fed. R. Evid. 803(8). As such, under Fed. R. Evid. 901(b)(7), they should be deemed authentic without the need for further identification or authentication. These documents are relevant because they reflect the state of the prior art as of 1983-1984, the relevant time period

Category D, Document Number 28, consists of an annual report from the United States Renal Data Service. As a commercial publication or market report, this document falls within an exception to hearsay under Fed. R. Evid. 803(17). The document is also self-authenticating under Fed R. Evid 902(5) as a commercial publication issued by a public authority. The report is relevant because it provides objective evidence of non-obviousness as of 1983-1984, the relevant time period.

For the reasons set forth above, Amgen moves to have the documents set forth in the attached chart moved into evidence in this case.

Dated: October 1, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 and paper copies will be sent to those indicated as non-registered participants on October 1, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried

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," *Thromb. Haemostasis* 46, 658-661 (1981)	Prior art
3.	DSB	07/00/1981	Lodish, "Post-Translational Modification of Proteins," *Enzyme Microb Technol.* 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 *et al.*, "Effects of Glycosidase Treatment on the Physiochemical Properties and Biological Activity of Human Interferon-γ" *J. Biol. Chem.* 258:8010-13 (1983)	Prior art

LIST OF EXHIBITS

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

LIST OF EXHIBITS

Tab	Ex. #	Date	Description	Relevance
13.	DCD	00/00/1985	Mueckler et al., "Sequence and structure of a human glucose transporter," *Science*, 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.

LIST OF EXHIBITS

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")

A

LIST OF EXHIBITS

Tab	Ex. #	Date	Description	Relevance
16.	CUE	00/00/1986	Erslev, A.J., and Caro, J., "Physiologic and molecular biology of erythropoietin," *Med. Oncol. Tumor. Pharmacother.* 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 *in vitro* 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).")

LIST OF EXHIBITS

	Tab	Ex. #	Date	Description	Relevance
A	19.	CVS	07/00/1983	Fisher. Control of erythropoietin production. Proc Soc Exp Biol. Med. 1983 Jul;173(3):289-305	Prior art
D	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.
D	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.
D	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.
D	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.
D	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.)

A

LIST OF EXHIBITS

PUBLIC RECORDS (CATEGORY 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")

LIST OF EXHIBITS

Tab	Ex.#	Date	Description	Relevance
27.	AHQ	11/21/1996	Paper 6, "Amendment," from certified file history of U.S. Patent No. 5,753,486	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**
D **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

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMANN LAROCHE INC., Defendants.	)	Civil Action No.: 05 Civ. 12237 WGY

DECLARATION OF WYETH REGARDING PRODUCED DOCUMENTS

I, Christopher Chung, declare:

1. I am employed as a Senior Patent Attorney by WYETH. My office address is 87 CambridgePark Drive, Cambridge, MA.

2. I make this declaration of my own personal knowledge. If called to testify as to the truth of the matters stated herein, I could and would do so competently.

3. In response to a subpoena for documents in this case, a search for documents at WYETH (which is the successor to Genetics Institute, Inc.) was conducted, resulting in the documents that were produced pursuant to the subpoena.

4. The documents produced in response to the subpoena bear production numbers W01022, W01025, W01040-1041 ("Documents").

5. The Documents are true and correct copies of three agreements, which were discovered in WYETH's offices in the files of WYETH's legal department, which is the place, where if authentic, I would expect these agreements to be found.

6. The Documents, as discovered in the files of WYETH's legal department, were found in a file in such a condition as to create no suspicion concerning their authenticity.

7. The dates on the face of the Documents indicate that the Documents were in existence for more than twenty years.

8. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge.

Signed this 31st day of August, 2007.

By: _____
Name: Christopher Chung
Title: Senior Patent Attorney

CERTIFICATE OF SERVICE

I hereby certify that the Declaration of Wyeth Regarding Produced Documents was served upon the attorneys of record for the defendants (as listed below) via hand delivery and electronic mail on September 5, 2007.

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c/o Metro Meeting Centers – Boston
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Irasema Virrueta

ALBERT EINSTEIN COLLEGE OF MEDICINE
OF YESHIVA UNIVERSITY

1300 MORRIS PARK AVENUE, BRONX, N.Y. 10461 CABLE:EINCOLLMED, N.Y.

DEPARTMENT OF MEDICINE PHONE:(212) 430-2000

April 11, 1985

Dr. Ed Fritsch
Genetics Institute
87 Cambridge Park Drive
Cambridge, Massachusetts 02140

Dear Ed:

I am writing to request that you and Genetics Institute continue to retain samples of my human renal carcinoma cell line (as defined in the original "Sponsored Research Agreement"), in order to provide a second storage site for these cells. The cells should be maintained frozen, with periodic culturing if possible, to provide new cells for freezing.

These cells should not be provided to anyone other than myself and Dr. Dani Shouval.

Please acknowledge acceptance of these conditions.

Sincerely,

Judith B. Sherwood

Judith B. Sherwood, Ph.D.
Assistant Professor of Medicine

JBS/lce

Above conditions agreed to:

Edwood Fritsch

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W01022

Exhibit FJZ
05-12237-WGY

Genetics Institute

August 23, 1984

Albert Einstein College of
Medicine at Yeshiva University
1300 Morris Park Avenue
Bronx, New York 10461

Attention Dr. Sidney Goldfisher

Dear Sidney:

As we have discussed, Genetics Institute, Inc. ("GI") was not able to express EPO from the cell-line provided to us by Albert Einstein College of Medicine ("AECOM") under our agreement dated October 31, 1983 (the "Agreement"). We are therefore returning the cell-line to AECOM, and believe that it would be appropriate for us at this time to clarify the ongoing relationship of GI and AECOM.

GI is willing to continue to fund research at AECOM under the terms of the Agreement. However, since no "Products", as defined in the Agreement, have resulted or will result from the research of GI involving the cell-line provided to us, GI shall have no obligation to pay any royalties to AECOM under the Agreement.

Please indicate your acceptance to these terms by signing and returning this letter to me.

Sincerely,

Gabe Schmergel

Gabriel Schmergel
President

GS:emo

AGREED TO:

ALBERT EINSTEIN COLLEGE OF MEDICINE
AT YESHIVA UNIVERSITY

By: _____

cc: J. Sherwood

CONFIDENTIAL
W01025

225 Longwood Avenue
Boston, Massachusetts 02115
Telephone 617 232-6886
Telex 949219

Exhibit FJI
05-12237-WGY

October 26, 1983

Genetics Institute, Inc.
225 Longwood Avenue
Boston, MA 02115

Gentlemen:

In connection with the Sponsored Research Agreement of even date herewith (the "Research Agreement") between Genetics Institute, Inc. ("Genetics") and Albert Einstein College of Medicine of Yeshiva University, a division of Yeshiva University ("AECOM"), this letter is to confirm the following:

1. I shall be bound by the provisions of Section 2(c), 4 and 9 of the Research Agreement to the same extent as if I were a party to the Research Agreement.

2. I have not provided the Cell Line (as defined in the Research Agreement), or any part thereof, to any party (other than AECOM and Daniel Shouval).

3. My performance under this Agreement and under the Research Agreement shall not breach any obligations which I may have to any third party.

11/1/83 G.J. 11/8/83

4. During the term of the Research Agreement, I shall not directly or indirectly perform research in the field of erythropoiesis for any commercial third party.

5. I understand that, during the term of the Research Agreement, Genetics will pay consulting fees to me at the rate of $6,000 per annum and, in consideration thereof, I shall consult with Genetics in the Field of Research. Such consulting services shall involve not more than six days of consulting per year at the facilities of Genetics in Massachusetts, plus telephone consultations. Genetics shall reimburse me for reasonable travel, lodging, telephone and similar out-of-pocket expenses incurred by me in connection with my performance of such consulting services for Genetics.

6. Genetics shall grant to me a non-qualified stock option for the purchase of 500 shares of Common Stock of Genetics, at an exercise price of $20.00 per share, vesting in five equal installments of 100 shares each at the end of each six-month period commencing on the date hereof.

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W01040

7. Any invention or discovery, whether or not patentable, which relates to the Field of Research and which is conceived or reduced to practice by me, solely or jointly with others, in the performance of my consulting services for Genetics shall be treated as if it were conceived or reduced to practice by AECOM under the Research Agreement and shall be subject to all of the terms and conditions of the Research Agreement. It is understood, however, that all obligations of Genetics to pay royalties with respect to any such invention or discovery shall be solely as set forth in the Research Agreement.

Very truly yours,

Judith B. Sherwood, Ph.D.
Dr. Judy Sherwood

Agreed to:

Genetics Institute, Inc.

By: Gabriel Schmergel