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

ROCHE'S OPPOSITION TO AMGEN'S MOTION TO ADMIT EXHIBITS INTO EVIDENCE

Amgen's motion seeking admission of a raft of journal articles, incomplete portions of irrelevant documents, unauthenticated third party documents, and documents containing multiple layers of hearsay -- all with no sponsoring witness -- should be rejected as a transparent attempt to avoid using its trial time to attempt put evidence in through witnesses. Amgen's gambit should be rejected because there are multiple reasons that each document is not admissible at trial. Roche appends hereto a chart setting forth its specific objections to each document that Amgen proffers. However, there are several broad points that pertain to Amgen's proposed exhibits that warrant discussion.

Amgen Cannot Proffer Prior Art or Documents Regarding the State of the Art

Amgen claims that numerous of its proposed exhibits are admissible either as prior art or as evidence of the state of the art during the relevant time period. The articles that Amgen offers are not admissible because they cannot be relevant. As the patent holder, Amgen cannot

invalidate its own patents, and consequently cannot submit evidence of the prior art or state of the prior art. Section 282 by its terms allows for the introduction at trial of prior art and documents "showing the state of the art" only if there is notice in the pleadings or in writing of the publications being relied upon. 35 U.S.C. §282. Because it failed to file a notice pursuant to section 282, Amgen cannot present evidence at trial of either prior art or publications showing the state of the art. Amgen contends that 25 of Amgen's 28 proposed exhibits are relevant as either prior art or reflective of the state of the art . Given the clear mandates of section 282, Amgen may not obtain admission of any of these documents on that basis.

In addition, Amgen includes a number of proposed exhibits created after November 1984, and thus cannot constitute evidence of the prior art. (Tabs 12-18).

Amgen Fails to Demonstrate How Any Articles Are Evidence of Non-Obviousness

Amgen conclusorily contends that certain documents on its list of proposed exhibit list (Tabs 20-23, 28) are admissible because they constitute evidence of non-obviousness as of 1983-84. Yet, Amgen fails to explain how even one of these proposed exhibits are relevant to any one of the nine factors of non-obviousness delineated by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Amgen offers no explanation in its motion how any of these proposed exhibits are relevant to the *Graham* factors of non-obviousness.

Amgen Cannot Move Articles Relied Upon By its Expert Dr. Lodish Without His Testimony

Amgen's list of articles have been relief upon by their experts, particularly Dr. Lodish, who has been identified as Amgen's trial witness. Indeed, many of the articles are authored by him, and Dr. Lodish claims to have relied on most of the articles in support of his opinions in one of his expert reports. Yet rather than presenting these articles during his testimony under the learned treatise exception of FRE 803(18), which notably precludes the article from being

admitted, Amgen does an end round and seeks actual admission of these articles without basis (see section on ancient documents, *infra*). The Court should not countenance Amgen's tactic and preclude it from offering evidence that it chose not to introduce with its testifying expert in order to save trial time.

Amgen May Not Rely on the Ancient Documents Exception

Amgen contends that the first 24 of its 28 proposed exhibits are admissible under the "ancient documents" exception of FRE 803(16). Amgen has failed to show that any of these documents is covered by that exception.

Indeed, many of the documents on any of the documents contain hearsay within hearsay. therefore, they should not be admitted because each contains hearsay not subject to any exception. For example, the incomplete excerpts of the Genentech file history (Tab 15) contain hearsay statements regarding the content of scientific articles. In addition, every scientific article contains double hearsay statements regarding the findings of other cited scientific studies and articles.

It is well-established that the ancient documents exception "does not justify the admission of double hearsay merely because of its presence in an ancient document." *Hicks v. Charles Pfizer & Co.,* 466 F.Supp.2d 799, 806 (E.D.Tex. 2005). As the *Hicks* court stated "the danger of faulty perception persists unabated because a narrator, such as a reporter, may not properly record the remarks of the speaker." *Id.* Numerous other courts, including sister courts within the First Circuit, have similarly held that hearsay within ancient documents cannot be admitted, as Rule 805 plainly requires.. *See, e.g., United States v. Hajda*, 135 F.3d 439, 444 (7th Cir. 1998) ("if the [ancient] document contains more than one level of hearsay, an appropriate exception must be found for each level"); *Elmhart Indus. v. Home Ins. Co.*, __ F.Supp.2d __, 2007 WL

2782989 (D.R.I. Sept. 26, 2007) (excluding documents under the ancient documents exceptions that were "littered with admissibility issues" some of which contained "more than one level of hearsay").

Finally, it does not make sense to allow Amgen to get around the bar in the learned treatise exception to the admission of scientific articles relied upon by its experts, simply by denominating article over 20 years old as ancient documents. There is no basis to consider scientific articles written over 20 years ago to be more "truthful" than those written more recently. The rationale for the ancient documents exception -- that "age affords the assurance that the writing antedates the present controversy." FRE 803(16) (Advisory Comm. Notes) -- should not apply to scientific literature, which is presumably written without an eye towards any legal disputes.

Amgen Is Unable to Authenticate the Proposed Exhibits

Amgen fails to provide any evidence to authenticate many of the proposed exhibits that it seeks to admit. It has not authenticated third party documents, including those as to which it seeks admission as ancient documents. Federal Rule of Evidence 901(b)(8) provides a multi-pronged test to establish the authenticity of an ancient document. Under that test, it is Amgen's burden to "prove[] that the item is 20 years old, is in a condition that does not raise suspicions as to authenticity, ***and*** was found in a place of natural custody for such an item." 31 Wright & Miller § 7113 at 131 (2000). Amgen fails to explain how it meets this test as to documents that are not periodicals that it claims are ancient.

* * *

In addition, as set forth on the accompanying chart, many of the proposed exhibits are incomplete and should not be admitted and concern patently irrelevant matters.

CONCLUSION

For the foregoing reasons, the Court should deny Amgen's Motion to Admit Exhibits Into Evidence in its entirety.

Dated: October 2, 2007
Boston, Massachusetts

Respectfully submitted,

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ROCHE DIAGNOSTICS GMBH, and
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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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EXHIBIT CHART WITH DEFENDANTS' OBJECTIONS

Amgen, Inc. v. F. Hoffman-LaRoche Ltd. et al.
Case No. 1:05CV12237 WGY

(CATEGORY A)				
Tab	**Ex.#**	**Date**	**Description**	**Basis for Objection**
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)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; double hearsay.
2.	DRF	00/00/1981	Korninger, C., *et al.*, "Turnover of Human Extrinsic Plasminogen Activator in Rabbits," *Thormb. Haemostasis* 46, 658-661 (1981)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
3.	DSB	07/00/1981	Lodish, "Post-Translational Modification of Proteins," *Enzyme Microb Technol.* 1981 Jul: 3(3):177-280, at 186	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report, double hearsay..
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)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
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)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
6.	DRC	00/00/1983	Konrad, M. *et al*., "Applications of genetic engineering to the pharmaceutical	Amgen cannot introduce prior art; improper ancient document; improper

			industry," *Ann n Y Acad Sci.* 413:12-22 (1983)	to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
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)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
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)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
9.	CXJ	04/00/1984	Hagiwara, et al., "Erythorpoietin production in a primary culture of human renal carcinoma cells maintained in nude mice." *Blood* 63(4):828-835 (1984)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
10.	DAH	00/00/1984	Little, S.P., *et al.,* "Functional Properties of Carbohydrate Depleted Tissue Plasminogen Activator," *Biochemistry* 23, 6191-6195 (1984)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; double hearsay
11.	DCI	00/00/1984	Nilsson, T., *et al.,* "*In vivo* metabolism of human tissue-type plasm" *Scand J. Haematol.* 33, 49-53 (1984)	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report double hearsay
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	Postdates November 1984; Irrelevant because the paper is not on EPO, but a murine band 3 protein, which is not a hormone; Amgen cannot introduce documents regarding the state of the

				art; improper ancient document; improper to admit without sponsoring witness double hearsay.
13.	DCD	00/00/1985	Mueckler et al., "Sequence and structure of a human glucose transporter," *Science*, Vol. 229, pp. 941-5	Postdates November 1984; Irrelevant because not an article on EPO, but a human glucose transporter, which is not a hormone; Amgen cannot introduce documents regarding state of the art; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report double hearsay
14.	GWW	02/25/1985	Spiess et al., "Sequence of Human Asialoglycoprotein Receptor cDNA", Jounal of Bio Chem., 260:pp. 1979-1982	Postdates November 1984; Irrelevant because not an article on EPO, but a human asialoglycoprotein receptor; Amgen cannot introduce documents regarding state of the art; improper ancient document; improper to admit without sponsoring witness; double hearsay
15.	ABZ	10/21/1985	Paper 16, "Amendment," from certified file history of U.S. Patent No. 4,766,075	Postdates November 1984; Incomplete document; Not authenticated as an ancient document; hearsay within hearsay; irrelevant as it is a file history of Genentech; improper ancient document; improper to admit without sponsoring witness; Amgen cannot introduce documents regarding the state of the art double hearsay
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)	Postdates November 1984; Irrelevant as state of the art because it does not discuss the cloning and expression of DNA, only EPO's mechanism within

				the body; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; Amgen cannot introduce documents regarding the state of the art double hearsay
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)	Postdates November 1984; Irrelevant because it concerns tPA not EPO; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; Amgen cannot introduce documents regarding the state of the art; double hearsay
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)	Postdates November 1984; Irrelevant because it concerns tPA not EPO; improper ancient document; improper to admit without sponsoring witness; relied upon by Dr. Lodish in his expert report; Amgen cannot introduce documents regarding the state of the art; double hearsay
19.	CVS	07/00/1983	Fisher. Control of erythropoietin production. Proc Soc Exp. Biol. Med. 1983 Jul;173(3):289-305	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness.;double hearsay
20.	DNJ	00/00/1980	Fisher. Mechanism of the anemia of chronic renal failure. Nephron. 1980; 25(3):106-11	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness;; irrelevant to objective evidence of non-obviousness; double hearsay
21.	GWL	00/00/1967	Van Dyke et al., Erythropoietin Therapy in the Renoprival Pateint, U.S. Atomic	Amgen cannot introduce prior art; improper ancient document; improper

			Energy Commission, UCRL (1967) 17481:127-132	to admit without sponsoring witness;; irrelevant to objective evidence of non-obviousness; double hearsay
22.	DTL	08/00/1971	Nakao et al. Erythorpoiesis in anephric or kidney transplanted pateints. Isr. J. Med. Sci. 1971 Jul-Aug; 7(7): 986-90	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness;; irrelevant to objective evidence of non-obviousness; double hearsay
23.	DMJ	04/15/1971	Erslev. The search for erythropoietin. N. Engl. J. Med. 1971 Jul-Aug;7(7):986-90	Amgen cannot introduce prior art; improper ancient document; improper to admit without sponsoring witness;; irrelevant to objective evidence of non-obviousness; double hearsay
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)	Failure to authenticate as an ancient document; hearsay; irrelevant.

(CATEGORY B)				
Tab	**Ex.#**	**Date**	**Description**	**Basis for Objection**
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)	Irrelevant; cannot constitute state of the art evidence since the document is dated in 2001

(CATEGORY C)				
Tab	**Ex.#**	**Date**	**Description**	**Basis for Objection**
26.	AHF	07/02/1996	Paper 6, "Amendment," from certified file history of U.S. Patent No. 5,869,314	Hearsay; lack of authentication; incomplete document; Amgen cannot introduce documents regarding the

				stateof the art; Irrelevant as a Genentech file history
27.	AHQ	11/21/1996	Paper 6, "Amendment," from certified file history of U.S. Patent No. 5,753,486	Hearsay; lack of authentication; incomplete document; Amgen cannot introduce documents regarding the stateof the art; Irrelevant as a Genentech file history

(CATEGORY D)				
Tab	**Ex.#**	**Date**	**Description**	**Basis for Objection**
28.	FUP	2006	US Renal Data Service Annual Report on incidence of ESRD (2006)	Irrelevant to objective evidence of non-obviousness; no foundation for admission under FRE 803(17); lack of authentication; hearsay