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-CV-12237 WGY

ROCHE'S MEMORANDUM IN OPPOSITION TO AMGEN'S MOTION TO ADMIT LIST OF EXHIBITS INTO EVIDENCE FOR INFRINGEMENT PHASE OF TRIAL

Amgen's motion (D.I. 1239) seeking preadmission of a large collection of documents purportedly relating to the infringement phase of trial should be rejected as yet another attempt by Amgen to avoid using its trial time to properly lay foundation through testifying witnesses for documents it wishes to enter into evidence. Especially in the context of technical documents, which may be misinterpreted by the lay juror, evidentiary rules provide an important safeguard against admission of irrelevant and potentially misleading or confusing information. It is therefore especially important in that proper foundation be established before any such document is admitted into evidence.

Roche generally objects to preadmission as Amgen has not established that any of these documents is relevant and therefore admissible under Fed. R. Evid. 402, and there is no certainty that Amgen will be able to do so. Additionally, there are specific

reasons for why each of these documents should not be admissible at trial. Roche appends hereto a chart setting forth its specific objections to each document, and addresses some of these reasons in more detail below.

Amgen Cannot Proffer Exhibits It Failed To Properly Identify on its Exhibit List

Specifically, Roche objects to the admission of exhibits GXB, GXC, GXD , GXD, GXE and GXF on the grounds that they were not previously identified on Amgen's exhibit list. Therefore this proffer is in violation of the Court's pretrial procedures pursuant to Local Rule 16.5.

Documents for which Amgen Has Not Established a Nexus to Its Infringement Contentions

While this objection applies generally to all the documents that Amgen wishes to proffer (as detailed in the attached exhibit chart), additionally, it should not be presumed that documents falling into any particular category are necessarily relevant. Amgen must articulate specific reasons why a particular document is relevant.

For example, Roche objects under Fed. R. Evid. 402 to the admission of exhibits which constitute "regulatory documents," for example, GXB, GXD, EPH, EPV, EVI . Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Roche's extensive regulatory filings include many documents on diverse topics. Amgen has not demonstrated a nexus between any of these documents and issues of infringement.

Roche further objects to the admission of documents relating to various scientific studies relating to other compounds, and which have no information relating to either the accused product or to the purified epoetin beta starting reagent used in the manufacture of

CERA, as irrelevant under Fed. R. Evid. 402. Such documents include EOE, EOI, EOJ, EPI, EXI, ESU Additionally, no foundation has been established for why EZC, an "artistic view" of a molecule, which the document on its face indicates was not based on EPO, but on a molecule with three changed amino acids, has any relevance to the accused product or issue of infringement. Similarly, Amgen has not articulated any specific ground for the relevance of various e-mails, including EOM, ETO, EZH, EZL and FGN.

Roche also objects to Amgen's admission of any evidence relating to pegylation of non-EPO compounds (exhibit CQX) for the reasons set forth in Roche's Bench Memorandum to Preclude Amgen from Introducing Testimony Related to Pegylation of Non-EPO Compounds (D.I. 1260), including relevance under Fed. R. Evid. 402. Briefly, Amgen refused to provide discovery into Amgen's work involving pegylation of any non-EPO molecule as irrelevant to infringement and not at issue in this case. Consistent with this Court's ruling that "no witness may rely on evidence withheld from discovery," Amgen should be barred now from raising this evidence before the jury.

Irrelevant Information Relating to Cell Lines Used by Chugai or GI

In addition to any other applicable objection, Roche specifically objects to the admission of exhibits EAZ-1 and EBA-1 to the extent there is reference to any relationship between the cell lines used by Roche and either Chugai or GI for the reasons set forth in Roche's Motion *In Limine* To Preclude Amgen Expert Harvey Lodish From Giving irrelevant Testimony Related To Cell Lines (D.I. 1244).

Documents Containing Multiple Levels of Hearsay

Exhibits BEG, EXI, EZC and EZD are PowerPoint-type presentations of unidentified authorship, which contain statements as to the content of various studies or articles. Moreover, in view of the lack of context, there is no indication as to how these documents are relevant. Similarly, exhibits EOI, EOM, ESU, ETO, EWU, EZH, EZL and FGN, are assorted pieces of correspondence, which include statements as to the content of other documents or conversations. Although the Court has held these documents themselves as admissions, Amgen has not established that all hearsay statements contained within each these documents also constitute admissions under Fed. R. Evid. 801(d)(2). Any such statement not within the scope of 801(d)(2) is inadmissible hearsay.

Roche reserves the right to offer additional objections at a later time.

DATED: October 3, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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and
HOFFMANN-LA ROCHE INC.
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/s/ Thomas F. Fleming

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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.

/s/ Thomas F. Fleming
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EXHIBIT CHART WITH DEFENDANTS' OBJECTIONS

NON-INFRINGEMENT EXHIBITS AMGEN SEEKS FOR PREADMISSION (D.I. 1239)

EX.	DATE	DESCRIPTION	OBJECTIONS
BEG		CERA Investor Telephone Conf., November 17, 2003	FRE 402, 801/802 Amgen has not shown that this document is relevant to infringement, contains nested hearsay.
CQX	11/00/1998	Bailon et al., "Polyethylene Glycol-Conjugated Pharmaceutical Proteins," PSTT Vol. 1, No. 8, 1998.	FRE 402/403, 801/802 This review article, published before Roche developed CERA, has no discussion of EPO or pegylation of EPO. Amgen should be precluded from introducing this document for the reasons summarized in Roche's Bench memorandum (DI 1260), contains nested hearsay.
EOE	8/20/2003	B. Bethell e-mail to M. Huber, Subject: SEP Phase 1 SAD Study, dated August 20, 2003	FRE 402 Amgen has not shown this document is relevant to infringement, information in the document does not relate to the product Amgen accuses of infringement
EOI	6/28/1995	Certified English Translation of Memo from Koll to Scherhag re Cangene - Pegyliertes EPO	FRE 402 Amgen has not shown that this document is relevant to infringement, information in the document does not relate to the product Amgen accuses of infringement
EOJ	8/22/2001	Comments to CMC of SEP 1-B51	FRE 402 Amgen has not shown that this document is relevant to infringement, information in the document does not relate to the product Amgen accuses of infringement
EOM	10/27/1999	Email from Bailon to Kin re Expert Opinion on Genotox Test Requirement for PEG-EPO	FRE 802, 402 Contains nested hearsay, Amgen has not shown that this document is relevant to infringement
EPH	8/17/2001	Report No. 1005851 Regulatory Document, "Long-Lasting Forms of Polyethyleneglycol Conjugated Erythropoietin (PEG-EPO)"	FRE 402 Amgen has not shown that this document is relevant to infringement or that the information in the document relates to the actual product Amgen accuses of infringement

EX.	DATE	DESCRIPTION	OBJECTIONS
EPI		SEP Project RDC 1-06/13/2002	FRE 402 Amgen has not shown that this document is relevant to infringement, information in the document does not relate to the product Amgen accuses of infringement; authorless document provides no context for relevance
EPV	9/26/2005	An Investigation into the Signaling Pathways Activated by Continuous Erythropoiesis Receptor Activator (CERA) Progress Report #1, September 26, 2005	FRE 402, 801/802 Amgen has not shown that this document is relevant to infringement, contains nested hearsay
ESU	6/28/1995	Memo from Koll to Scherhag re Cangene - Pegyliertes EPO	FRE 402 Amgen has not shown that this document is relevant to infringement, information in the document does not relate to the product Amgen accuses of infringement
ETO	9/22/2006	Email from Jarsch to Haselbeck re Module 4: Non Clinical, Question No. 55: Non Clinical Pharmacology	FRE 402, 801/802 Amgen has not shown that this document is relevant to infringement, contains nested hearsay.
EVI	2/21/2001	Patient Informated Consent Form, Roche Protocol No. BA 16260 (Version A)	FRE 402 Amgen has not shown that this document is relevant to infringement
EWU	1/26/2006	Email from Jarsch to Escrig re CERA MOA Abstract for EDTA	FRE 402 Amgen has not shown that this document is relevant to infringement
EXI	1/22/2005	Pre-Clinical Studies on Mode of Action: Summary of Advisory Board, Jan, 22, NY	FRE 801/802, 402 Amgen has not shown that this document is relevant to infringement, contains nested hearsay.
EZC		CERA Modelling Penzberg	FRE 801/802, 402 Amgen has not shown that this document is relevant to infringement, information in the document does not relate to the product Amgen accuses of infringement; contains nested hearsay.
EZD		CERA Physical and Chemical Characterization	FRE 801/802, 402 Contains nested hearsay with no particular declarant identified; Amgen has not shown that this document is relevant to infringement.

EX.	DATE	DESCRIPTION	OBJECTIONS
EZH	11/4/1999	Email from Bailon to Farid re Description of PEG-EPO	FRE 402, 801/802 Contains nested hearsay with no particular declarant identified; Amgen has not shown that this document is relevant to infringement.
EZL	2/3/2004	Email from Haselbeck to Escrig re Slide for Macdougall about the EPO and CERA and EPO-R	FRE 402, 801/802 Contains nested hearsay with no particular declarant identified; Amgen has not shown that this document is relevant to infringement.
FGN	2/18/2002	Email from Bailon to Ehrlich re EPO & PEG-EPO	FRE 402, 801/802 Contains nested hearsay with no particular declarant identified; Amgen has not shown that this document is relevant to infringement.
BLA/IND			
GXE	4/18/2006	Letter Submitting BLA for MIRCERA, Form 356h, Table of Contents and Roadmap of BLA	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Not timely disclosed on Amgen's exhibit list.
GXF		Information for Patients and Caregivers, MIRCERA pegserepoetin alfa FOR INJECTION	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Not timely disclosed on Amgen's exhibit list.
EAZ-1		Drug Substance - R00503821 • ITC-R-BLA 00004024 - 4032 • ITC-R-BLA 00004232 - 4244 • ITC-R-BLA 0000 4324 - 4330	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Roche specifically objects to the admission of exhibits EAZ-1 and EBA-1 to the extent there is reference to any relationship between the cell lines used by Roche and either Chugai or GI
EBA-1		Drug Substance - EPO Starting Material • ITC-R-BLA 00004651 - 4662 • ITC-R-BLA 00004667 - 4669 • ITC-R-BLA 00004722 - 4740 • ITC-R-BLA 00004803 - 4857 • ITC-R-BLA 00004987 - 4988 • ITC-R-BLA 00005073 - 5074 • ITC-R-BLA 00005580 - 5581 • ITC-R-BLA 00005616 - 5619	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Roche specifically objects to the admission of exhibits EAZ-1 and EBA-1 to the extent there is reference to any relationship between the cell lines used by Roche and either Chugai or GI

EX.	DATE	DESCRIPTION	OBJECTIONS
GXB		Section 2.7.2 of Roche's BLA - Summary of Clinical Pharmacology Studies	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Not timely disclosed on Amgen's exhibit list.
GXD	8/16/2004	Report No. 1012588, Regulatory Document, RO0503821-000: *In vivo* stability and tissue localization of RO050381 after single (IV or SC) or multiple (IV) dose administration to rats (Study Nos. D01017 and D02001)	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Not timely disclosed on Amgen's exhibit list.
GXC		Investigational New Drug Application, Form 1571 for RO50-3821, and Letter Submitting IND	FRE 402 Relevance cannot be presumed merely because a document was included in Roche's regulatory filings. Not timely disclosed on Amgen's exhibit list.