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-12237 WGY

DEFENDANTS' *OMNIBUS* MOTION TO ADMIT PARTY ADMISSIONS AND PREVIOUS FINDINGS OF FACT INTO EVIDENCE

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") request that the following admissions by Amgen and findings of fact from prior litigations to which Amgen was a party be read into evidence. Reading this evidence into the record will present the issues to the jury in an orderly, economical way.

I. Responses to Requests for Admissions

A. *Amgen v. F. Hoffman-La Roche Ltd*, 05-CV-12237 WGY (D. Mass.)

The following responses by Amgen from "Plaintiff Amgen Inc.'s Responses To Defendant's Third Set Of Requests For Admissions (Nos. 19-40)" dated April 2, 2007 are binding admissions pursuant to Fed. R. Civ. P. 36:

REQUEST FOR ADMISSION NO. 32.

Admit that both rHuEPO and u-EPO are capable of increasing hemoglobin synthesis after in vivo administration to mice.

RESPONSE TO REQUEST FOR ADMISSION NO. 32:

In addition to the foregoing General Objections, Amgen makes the following Specific

Objections to this Request: Amgen objects to the request because the terms "u-HuEPO," "r-HuEPO," and "capable of," as Defendants use them in this request, are vague, ambiguous, overly broad, and subject to disputed and varied definitions. Consequently, this request is insufficiently precise and lacks information upon which to admit the request according to the Federal Rule of Civil Procedure 36. Amgen objects to this request because it is premature and calls for expert testimony.

Subject to the foregoing General and Specific Objections, Amgen admits that both Dr. Lin's claimed recombinant human erythropoietin products and the human urinary erythropoietin preparation purified by Drs. Miyake and Goldwasser as described in Miyake, et al., *J. Biol. Chem.*, 252, 5558-5564 (1977) have caused increased hemoglobin synthesis after in vivo administration to mice. Amgen otherwise denies Roche's Request for Admission No. 32. (RFA, p. 18).

B. *Amgen v Chugai Pharm.*, 87-2617-Y (D. Mass.)

The following responses by Amgen from "Amgen's Answers to Chugai Pharmaceutical Co., Ltd.'s Request for Admissions" dated July 7, 1989 are party admissions pursuant to Fed. R. Evid. 801(d)(2):

144. Once Amgen had the tryptic fragment amino acid sequence information obtained from Dr. Goldwasser's EPO sample, it only took Amgen approximately two and half months to identify the positive clones.

RESPONSE TO REQUEST NO. 144:

Admitted. AM-ITC 00123616

147. Dr. Lin did not purify the EPO fragments. (F. Lin Boston Deposition at 181).

RESPONSE TO REQUEST NO. 147:

Admitted. AM-ITC 00123617

148. Dr. Lin did not sequence the EPO fragments. (F. Lin Boston Deposition at 181).

RESPONSE TO REQUEST NO. 148:

Admitted. AM-ITC 00123617

183. As of 1982, if a researcher were able to identify the true positive out of the putative clones, it was obvious that he would succeed in determining the DNA nucleotide sequence for that clone.

RESPONSE TO REQUEST NO. 183:

Admitted. AM-ITC 00123630

210. It took Dr. Lin only about an hour to specify the probes because it was known how to specify probes once you have the amino acid sequence.

RESPONSE TO REQUEST NO. 210:

Admitted. AM-ITC 00123639

437. There appear to be no differences in the secondary structure of EPO produced in a CHO cell versus EPO produced in a human kidney cell.

RESPONSE TO REQUEST NO. 437:

Admitted. AM-ITC 00123714

II. Findings of Fact From Previous Litigation to Which Amgen Was a Party

Roche requests that this Court take judicial notice of the following findings of fact pursuant to Fed. R. Evid. 201 and admit those facts into evidence for consideration by the jury. *Kowalski v. Gagne*, 914 F.2d 299, 305 (1st Cir. 1990) ("It is well-accepted that federal courts may

take judicial notice of proceedings in other courts if those proceedings have relevance to the matters at hand."); *N.L.R.B. v. Gass*, 377 F.2d 438, 442 (1st Cir. 1967) (taking judicial notice of admission and findings from prior proceeding).

A *Amgen v. Hoechst Marion Roussel*, 126 F. Supp. 2d 69 (D. Mass. 2001)

1. "Dr. Lin's disclosure [in the patents-in-suit] fails adequately to describe an EPO glycoprotein whose glycosylation differs from that of human urinary erythropoietin." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 155 (D. Mass. 2001).

2. "The Egrie Input included an SDS-PAGE gel that compared COS-1 produced recombinant EPO and Goldwasser's human urinary EPO standard. Dr. Egrie reported that these EPOs 'have the same molecular weight' and 'that the recombinant EPO is glycosylated to the same extent as the native protein.' The Egrie Input also included SDS-PAGE gels comparing CHO cell produced recombinant EPO and Lot 82 human urinary EPO; she explained that these gels indicated that the differing EPOs had the same molecular weight." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 141-142 (D. Mass. 2001) (internal citations omitted).

B. *Amgen, Inc. v. Chugai Pharm.*, 1989 WL 169006 (D. Mass. 1989)

1. "Dr. Lin himself testified that the use of two sets of probes or the use of fully degenerate probes was not particularly innovative." *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 1989 WL 169006 at *43 (internal citations to evidence omitted).

C. *In re Certain Recombinant Erythropoietin*, Investigation No. 337-TA-281

The following findings of fact are also set forth in admitted Trial Ex. 2012 (prosecution history of Ser. No. 113,179 which issued as U.S. 5,441,868):

"200. A CHO cell transfected with the DNA sequence encoding for EPO makes erythropoietin all the time and no signal is needed to begin production of erythropoietin." Trial Ex. 2012 at 2012.647 (AM-ITC 00953430)(citations to evidence omitted).

"365. Dr. Lin did not "choose" to develop the EPV and EPQ probes from the amino acid sequence information of fragments 35 and 38. He used fragments 35 and 38 to design his probes because they were among the first fragments to be sequenced." Trial Ex. 2012 at 2012.676 (AM-ITC 00953459)(citations to evidence omitted).

"400. There appear to be no differences in the secondary structure of EPO produced in a CHO cell versus EPO produced in a human kidney cell." Trial Ex. 2012 at 2012.682 (AM-ITC 00953465)(citations to evidence omitted).

"403. In terms of biological function. i.e., having the same effect on causing red cells to be produced in the body, recombinant EPO and natural EPO are the same." Trial Ex. 2012 at 2012.683 (AM-ITC 00953465)(citations to evidence omitted).

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 that no agreement could be reached.

DATED: September 13, 2007

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

By its attorneys,

/s/ Thomas F. Fleming

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky *(pro hac vice)*
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Krista M. Rycroft (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

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) on the above date.

/s/ *Thomas F. Fleming*
Thomas F. Fleming