UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 1:05-cv-12237 WGY

AMGEN'S BENCH MEMORANDUM REGARDING FRITSCH DEPOSITION TESTIMONY AND REQUEST FOR CORRECTIVE INSTRUCTION

At trial on September 7, 2007, Roche asserted in a side bar that the Dr. Fritsch testimony read into the record was (1) relevant Section 102(g) prior art and (2) admissible as evidence of a simultaneous invention.[1] The Court requested a bench memorandum from Amgen.[2] Neither ground Roche advanced in the side bar withstands scrutiny and Amgen requests that a corrective instruction be given that the Jury is to disregard the testimony of Dr. Fritsch and Dr. Lowe's opinion based thereon.[3]

Addressing the first ground, an invalidity defense under Sections 102(g)/103 requires that Roche establish by clear and convincing evidence that (1) another inventor, (2) reduced to practice an invention before the invention by Dr. Lin, or conceived of an invention before the invention by Dr. Lin followed by diligence to a reduction to practice, and (3) the prior reduction to practice or prior conception is supported by independent corroborating evidence.[4]

[1] Trial Transcript September 7, 2007 (Tr. 361:22-363:23).
[2] Trial Transcript September 7, 2007 (Tr. 363:3-8).
[3] Roche stated that it would offer the exhibits identified in Dr. Fritsch's testimony at a later date. To the extent Roche intends to offer such exhibits, Amgen objects as well.
[4] *See Sandt Technol. Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001).

To be admissible as relevant Section 102(g) prior art for purposes of showing obviousness, Roche must first show, backed by corroborating evidence, that Dr. Fritsch conceived of the EPO gene and other inventions on a date earlier than Dr. Lin's conception and reduction to practice of his EPO inventions.[5] Roche did not and cannot make this preliminary showing, and has failed to offer any evidence from Dr. Fritsch supporting a prior conception date to Dr. Lin's inventions.

"Conception is a question of law."[6] In *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, the Federal Circuit held that as a matter of law, "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated."[7]

Dr. Fritsch's testimony admitted that he did not isolate the EPO gene until August 20, 1984[8] and did not express EPO in CHO cells until September 1984,[9] approximately 10 months after Dr. Lin isolated the EPO gene and four months after Dr. Lin caused to be expressed EPO in CHO cells.[10] Thus, regardless of which parties were involved during the *Amgen v. Chugai* litigation, and which parties are currently involved here, as a matter of Federal Circuit law, the

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[5] 35 U.S.C. § 102(g)(2) ("A person shall be entitled a patent unless . . .[(g)(2)] before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.")

[6] *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

[7] 927 F.2d 1200, 1206 (Fed. Cir. 1991).

[8] Trial Transcript September 7, 2007 (355:19-356:17).

[9] Trial Transcript September 7, 2007 (360:5-360:21).

[10] *See Amgen v. Chugai*, 1989 U.S. Dist. LEXIS 16110, 13 U.S.P.Q. 2d 1737 (D. Mass. 1989). Pursuant to Fed. R. Evid. 201, Amgen requests that the Court take judicial notice of the adjudicative facts set forth in the attached 2 pages from Judge Saris' Opinion that:

1. The successful cloning of the EPO gene took place in early October 1983;
2. On February 13 and 14, 1984, Amgen conducted experiments to show the recombinant human EPO produced in Cos cells was biologically active;
3. By May 2, 1984, human rEPO had been expressed in CHO cells.

(Attachment A, hereto.)

EPO gene had to actually be isolated before a party could conceive of an invention containing the EPO gene. And as admitted, Dr. Fritsch did not isolate the EPO gene until after Dr. Lin's inventions. Roche has made no proffer to the contrary, and thus fails to establish the necessary fact to qualify this evidence as Section 102(g) prior art.

Moreover, Roche's interrogatory responses failed to disclose this testimony as Section 102(g) prior art for purposes of Section 103. Under Federal Rule of Civil Procedure 37(c), the testimony should be stricken.

Finally, the issue of priority was settled long ago by the Board of Patent Appeals and Interferences. This issue was adjudicated and lost by Dr. Fritsch. If the evidence is permitted, Roche is effectively undermining the presumption of validity that attaches to Lin's patents by using evidence and advancing arguments that were rejected. At a minimum, if it is admissible, the Jury should be informed of the result of the Interference awarding priority to Amgen.[11]

Dr. Fritsch's testimony also fails to be relevant evidence of a simultaneous invention. Evidence of a contemporaneous invention, in and of itself, is never sufficient to establish that an invention was obvious at the time that it was made.[12] Moreover, "contemporaneous development that occurs after the date of the patented invention, however, will almost never be probative of the ultimate conclusion of obviousness."[13] In the testimony read by Roche, Dr. Fritsch fully admitted that as a matter of law he conceived of the DNA sequence approximately 10 months after Dr. Lin successfully conceived of the EPO DNA sequence and approximately 8 months after Dr. Lin filed his initial patent application on his inventions on December 13, 1983.

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[11] Amgen requests that the Court take judicial notice of the adjudicative facts set forth in the attached U.S.P.Q. decisions. *See Fritsch v. Lin*, Patent Interference No. 102,096, 1991 Pat. App. LEXIS 29; *Fritsch v. Lin*, Patent Interference No. 102,097, 1991 Pat. App. LEXIS 30. (*See* Attachments B and C hereto.)

[12] *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 n.4 (Fed. Cir. 1986) (the simultaneous development of a similar invention may or may not be indicative of obviousness depending on the surrounding circumstances and the other evidence in the case.)

[13] *Eli Lilly & Co. v. Teva Pharms. U.S.A., Inc.*, 2004 U.S. Dist. LEXIS 14724, *120 (S.D. Ind. 2004); *see Hybritech*, 802 F.2d at 1380 n.4 (contemporaneous development a year after the filing date of a patent is "of little probative value").

Such later actions by Dr. Fritsch do not constitute evidence of a "contemporaneous" invention and offer no probative value to the obviousness inquiry.

Roche has already read Dr. Fritsch's prior testimony into the record. Thus, the proper action is for the Court to give an instruction to the jury that Dr. Fritsch's testimony and Dr. Lowe's opinions thereon are irrelevant to the issue of invalidity.

DATED: September 10, 2007

Respectfully Submitted,

AMGEN INC.,

/s/ Michael R. Gottfried

D. Dennis Allegretti (BBO# 545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (pro hac vice)
DAY CASEBEER MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede III (pro hac vice)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (pro hac vice)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

CERTIFICATE OF SERVICE

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/s/ Michael R. Gottfried

Michael R. Gottfried