

**IN THE UNITED STATES DISTRICT COURT
FOR THE 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. 05-12237 WGY

U.S. District Judge Young

**OPPOSITION TO AMGEN’S BENCH MEMORANDUM REGARDING
DR. LIN’S SUBJECTIVE EXPECTATIONS AS
IRRELEVANT TO A PROPER OBVIOUSNESS INQUIRY**

Contrary to Amgen’s assertions, the testimony Roche seeks to elicit regarding Dr. Lin’s subjective expectations is highly relevant and appropriate under controlling precedent. Roche intends to submit evidence and elicit testimony regarding Dr. Lin’s expectation of success in carrying out and developing his “inventions,” as this evidence is relevant to the state of the art and understanding what a person of ordinary skill in the art would have deemed obvious. The Court has already ruled on this issue in relation to Amgen’s Motion *in Limine* No. 24 (Trial Tr. at 271), and Roche submits that the Court’s denial of Amgen’s motion was proper.

The Federal Circuit has stated that the “inventors’ testimony [is] relevant to whether the inventions would have been obvious to a person of ordinary skill in the art.” *Neupak, Inc. v. Ideal Mfg. and Sales Corp.*, 2002 WL 1363568, *4 (Fed. Cir. June 24, 2002); *see also In re QED Envtl Sys., Inc.*, 991 F.2d 809 (Fed. Cir. 1993) (trial testimony of inventors was “extremely

relevant” to determining the “difference between what the inventors admit to be well known and the claimed subject matter” with respect to obviousness); *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (“conclusion [of obviousness] is further reinforced by testimony from the sole inventor at trial”); *Frazier v. Layne Christensen Co.*, 2007 WL 1875909, *1 (Fed. Cir. June 29, 2007) (considering inventor testimony in obviousness determination); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315-16 (Fed. Cir. 1985) (same); *Dystar Textilfarben GmbH & Co. v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006) (same); *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1364 (Fed. Cir. 2005) (same); *LNP Eng’g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1358 (Fed. Cir. 2001) (same).

In *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804 (Fed. Cir. 1989), the inventor claimed to have invented an effective therapeutic dose range for a drug combination taught in the prior art. “The evidence at trial showed that, though requiring time and care, the experimentation needed to arrive at the claimed dosages was nothing more than routine.” *Id.* at 809. The *Merck* case makes clear that the testimony of an inventor is highly relevant to determining what was expected from the prior art. The court noted that:

[i]t is to be expected that their co-administration would induce more sodium excretion than would either diuretic alone....Indeed, *the inventor named on both the ‘813 and ‘430 patents, so testified....When further questioned on the point, the inventor indicated that his uncertainty inhered not in the fact that an increase was to be expected, but only in the magnitude of the increase.*

Id. at 808-09 (emphasis added); *see also Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007), *reh’g denied*, 488 F.3d 1377 (Fed. Cir. 2007) (in determining success was not unexpected, inventor’s “testimony reflects the fact that he believed that” new chemical entity would solve deficiency in prior art). Accordingly, the Federal Circuit has repeatedly made clear

that the inventor's testimony regarding his own efforts and expectation of success is highly pertinent to understanding what one of ordinary skill in the art would have expected.

The correct standards of law relating to obviousness have been explained in the Supreme Court's recent holding in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741-42 (2007). The Court stated that in determining whether a particular invention is obvious in light of the prior art, the motivation of the inventor is one factor that must be considered. As the Court stated, "the problem motivating the patentee may be only one of many addressed by the patent's subject matter." *Id.* at 1742. While it is proper, even required, to look at a variety of factors in determining the obviousness of an invention and the reasonable expectation of success that a person of ordinary skill in the art may have, the inventor's own motivation and expectation of success is one of those factors. *Id.* at 1742. Clarifying prior Federal Circuit jurisprudence, the Court emphasized that "a person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *Id.* Because the person of ordinary skill in the art is a person who shows creativity, and does not just follow an instruction manual, the motivation and expectation of success of the inventor are important factors in determining the ultimate questions of reasonable expectation of success and motivation to combine elements in the prior art to determine obviousness of an invention.

Moreover, as Roche explained in its opposition to Amgen's Motion *in Limine* No. 24, Amgen itself put at issue the testimony and evidence it seeks to preclude in its opening statement to the jury. In its opening, Amgen informed the jury of Dr. Lin's state of mind, beliefs and expectations of success. Amgen told the jury that Dr. Lin "dreamed" of making EPO, and that he "worked day and night" to achieve his dream of making recombinant EPO, despite repeatedly failing to succeed. Amgen told the jury in opening arguments that Dr. Lin was so unsure of his

success in creating a biologically active protein that he allegedly devised three separate ways of expressing the protein: (1) bacterial expression; (2) yeast cell expression; and (3) mammalian expression. Amgen told the jury of Dr. Lin's expectations or lack thereof a mere hours after moving to have his testimony excluded. Although Amgen has no basis for excluding evidence of Dr. Lin's expectations, surely it has waived any objection it had by presenting these issues to the jury. Finally, as Roche previously explained, Amgen's experts repeatedly referred to Dr. Lin's expectations and state of mind in their expert reports. (D.I. 1001 at 5-7).

As Roche explained in its prior submission on this issue, Dr. Lin's beliefs, thoughts and expectations are highly relevant to his alleged conception and reduction to practice of the claimed "inventions." (D.I. 1001 at 7-8). The Court correctly allowed the jury to hear from Dr. Lowe regarding Dr. Lin's expectations of success. Surely, Dr. Lin's own testimony regarding his expectations of success are even more pertinent.

In accordance with this memorandum Roche respectfully submits that testimony and evidence from Dr. Lin regarding his expectations of success in developing the claimed inventions is relevant and an important factor for consideration in determining the reasonable expectation of success that one of skill in art would have and, ultimately, the issue of obviousness of the patents-in-suit.

DATED: September 11, 2007

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

By its attorneys,

/s/ Patricia A. Carson

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