

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

_____	)	
AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD,	)	
ROCHE DIAGNOSTICS GmbH	)	
and HOFFMANN-LA ROCHE INC.	)	
	)	
Defendants.	)	
_____	)	

**ROCHE’S OPPOSITION TO AMGEN’S BENCH MEMORANDUM  
REGARDING ITS PROPOSED JURY INSTRUCTION ON OBVIOUSNESS (DI 1335)**

Amgen’s proposed jury instruction on obviousness improperly states the law, ignores this Court’s prior rulings and would lead the jury into error on a number of grounds. For example, Amgen’s instruction would have the jury ignore Dr. Lin’s beliefs as to the state of the art and what was obvious at the time of his claimed invention. This is precisely the evidence that Amgen already unsuccessfully sought to have excluded. As this Court has ruled during trial, evidence of what Dr. Lin “thought [people] were doing and thought was going on,” is “proper evidence” for the jury to consider. (Trial Tr. 831). Indeed, early on in the proceedings, the Court denied Amgen’s motion in *limine* seeking to preclude such evidence (Trial Tr. 271). The Court’s rulings are supported by well-established Federal Circuit caselaw holding that an inventor’s beliefs as to the state of the art are relevant to an obviousness inquiry. Amgen’s proposed instruction, however, runs completely contrary to those cases and this Court’s rulings by directing the jury not to consider Dr. Lin’s views and beliefs as to the state of the art, and

what was obvious to a person of ordinary skill, at the time of his invention -- i.e., what he “thought was going on.” This Court should reject Amgen’s brazen attempt to have the Court again reconsider those rulings under the guise of a proposed instruction asking the jury to disregard admitted evidence.

Moreover, Amgen’s suggested obviousness instruction improperly seeks to have the jury disregard evidence admitted at trial of work done by Dr. Lin’s co-workers -- none of whom is an inventor here. As Roche explained in opposing Amgen bench memos unsuccessfully seeking to preclude this very testimony, evidence of the work done by co-workers is crucially relevant to show what one of ordinary skill in the art could do at the time. Finally, because the testimony about the activity leading to the claims at issue and the work by Dr. Lin’s co-workers are inextricably bound up with “how” the invention was made, the Court should reject Amgen’s requested charge that the jury ignore evidence on this point -- which Amgen itself raised by emphasizing Dr. Lin’s expectations and beliefs at the outset of trial.

**A. Amgen’s Requested Charge that the Jury Ignore Dr. Lin’s Beliefs on Obviousness and the State of the Art Is Contrary to Law and this Court’s Rulings**

In its proposed instructions, Amgen seeks to have the Court instruct the jury to disregard the “beliefs of the inventor, Dr. Lin, with respect to what he thought to be obvious at the time he conceived of the inventions.” (Amgen Proposed Instruction XIV(k) at 45). This proposed instruction is contrary to law and this Court’s prior rulings.

As the Federal Circuit has repeatedly made crystal clear, the inventor’s belief as to the state of the art is unquestionably relevant to determining obviousness. 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”); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315-16 (Fed. Cir. 1985) (considering inventor testimony in obviousness determination); *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).

Indeed, the Federal Circuit has ruled that an inventor’s testimony as to what he expected from the prior art is relevant. 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 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 ruling that success was not unexpected, inventor’s “testimony reflects the fact that he believed that” new chemical entity would solve deficiency in prior art).<sup>1</sup>

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<sup>1</sup> Contrary to Amgen’s argument, the law that an inventor’s belief as to the state of the art is relevant is not contradicted -- and, indeed, reinforced by the Court’s decision in *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727

This Court's rulings on the issue of Dr. Lin's beliefs are in line with this Federal Circuit precedent. At trial, the Court denied Amgen's motion in *limine* seeking to preclude Roche from eliciting testimony about the beliefs of Dr. Lin. (Trial Tr. 271, denying Amgen Motion in *Limine* No. 24). Later at trial, the Court made clear that Dr. Lin's beliefs as to the state of the art were relevant areas for inquiry, allowing for vigorous cross-examination of Dr. Lin of "what he knew then [at the time of the invention] and what he did then." (Trial Tr. 830). The Court noted that while the obviousness test is objective the issue of what Dr. Lin believed about "[w]hat people thought they were doing and thought was going on," was "proper evidence" for the jury to consider. (Trial Tr. 831).

Amgen's proposed instruction clearly runs afoul of this Court's rulings and Federal Circuit precedent by asking this Court to direct the jury "not to consider" Dr. Lin's beliefs about what he thought was obvious at the time he conceived his invention. In other words, Amgen incorrectly -- and without any legal support -- claims that the jury cannot hear what Dr. Lin thought at the time about what he knew, and what he knew others were doing -- classic testimony about the state of the art that the Federal Circuit has held is relevant in numerous cases.

**B. The Court Should Reject Amgen's Requested Charge That The Jury Ignore the Work of Dr. Lin's Co-Workers and Evidence of How the Invention Was Made**

Amgen's proposed instruction on obviousness is also faulty because it seeks to have the jury ignore relevant and admitted evidence about the work of other Amgen scientists in determining whether the claims are obvious. (Amgen Proposed Instruction XIV(k) at 45). The work done by Dr. Lin's co-workers is relevant to show what one of ordinary skill in the art could do at the time. None of Dr. Lin's co-workers is an inventor on Amgen's patents, so by Amgen's

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(2007). Amgen's selective quotations from that opinion fail to support its claim that the jury cannot consider the beliefs of Dr. Lin about the state of the relevant art. To the contrary, the Court in *KSR* held that a variety of factors should be considered in determining obviousness including the motivation of the patentee. 127 S.Ct. at 1742.

admission, they made no inventive contribution to any invention, if there was indeed an invention. The jury should be able to hear what they did as opposed to Dr. Lin so it can assess if Dr. Lin actually did anything described or claimed in Amgen's patents that was not obvious in light of the prior art. A court may look to the work of an inventor's employees in order to determine obviousness. *Omark Indust., Inc. v. Colonial Tool Co., Inc.*, 672 F.2d 362, 364 (3rd Cir. 1982). In finding the patent invalid for obviousness, the *Omark* court specifically looked to the techniques the inventor's employees used, at the time they made their "discovery", to determine what was present in the prior art. *Id.* Amgen -- having failed in its prior attempts to prevent the jury from hearing such evidence -- should not be allowed to have such evidence effectively stricken through its request for a jury instruction.

Moreover, the testimony at trial regarding the work of co-workers and how Dr. Lin's activities leading up to the claimed inventions are inextricably bound up with issue of how invention made. Ironically, Amgen presented at least two witnesses, Dr. Lin and Dr. Brown to testify regarding "how the invention was made," (Amgen Proposed Instruction XIV(k) at 45) yet now seeks an instruction barring the jury from considering this. Allowing Amgen's proposed instruction is not only unsupported legally, but also would be very confusing for the jury.

**C. Amgen Itself Put the Issue of the Subjective Motivation of Dr. Lin Before the Jury**

Finally, demonstrating that Amgen's requested charge should not be given, the Court should note that it is Amgen who first put at issue the subjective beliefs of Dr. Lin. As Roche explained in its opposition to Amgen's previous attempts to preclude evidence of Dr. Lin's beliefs and the work of non-inventor co-workers, 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. Although Amgen has no basis for preventing the jury from considering Dr. Lin’s beliefs and expectations, it has waived any objection it had by presenting these issues to the jury.

### CONCLUSION

For the foregoing reasons, the Court reject Amgen’s proposed instruction to the jury on obviousness.

Dated: October 11, 2007  
Boston, Massachusetts

Respectfully submitted,

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

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**CERTIFICATE OF SERVICE**

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/s/ Thomas F. Fleming  
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