

**IN THE UNITED STATES DISTRICT COURT
IN AND 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.: 1:05-cv-12237 WGY

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

The fact that an inventor expected his invention to succeed is legally irrelevant to the analysis of obviousness. The inventor is *not* the ordinarily skilled worker, and the fact that an inventor subjectively believed in the success of his or her invention is hardly objective evidence of establishing motivation to make the invention and a reasonable expectation of success on the part of an ordinarily skilled worker at the time.

To support its obviousness defense, Roche has identified statements made by Dr. Lin in his first patent application as to his expectation that EPO produced in microbial cells would be bioactive to support obviousness. Amgen anticipates that Roche will continue this line of questioning Dr. Lin. As the following example of questions and answers from Dr. Lowe’s testimony shows, Roche is attempting to bring Dr. Lin’s expectation into the obvious analysis:

Q. So when you take the whole picture together, all the information together, in your opinion, looking at just this claim as an example, where this claim -- I'm sorry, I have a small one, but that way I can actually hold it, it says the claim, the '868 claim, that the product will have in vivo activity, in vivo biological activity, *in your opinion, based on the prior art, based on what Dr. Lin said in his application*, would a person of

ordinary skill in the art expect reasonably whether there would be biological activity?

A. Yes.

Q. In your opinion, would that have been obvious?

A. Yes.

Q. In the 1984 application, the final application, the one that is actually in the patent, is the language from Example 7, let's go back to page 45, ***that language telling the patent office there will be an expectation that it would be biologically active***, was that paragraph put into the final application?

A. No.

(Daily Transcript of Evidence, Vol. 3, p. 278, ll. 1-20.)

It has long been held that the inventor's skill and his subjective beliefs that make up the act of conception are irrelevant to obviousness, and Roche's attempt to tie Dr. Lin's disclosed expectation to obviousness, as was done, is error.¹ This is because the fundamental test for obviousness, set forth in *Graham v. John Deere*, mandates that the inquiry be limited to:

[T]he scope and the content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt needs, failures of others, etc. might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.²

“While the sequence of these questions might be reorganized in any particular case, ***the factors continue to define the inquiry that controls.***”³

This inquiry does not invoke the inventor's subjective expectations, or the very evidence on which the inventor could rely to establish his conception and reduction to practice of his invention, but instead the objective person of ordinary skill in the art. It is improper to determine

¹ See *Standard Oil Co., v. American Cyanamid Co.*, 774 F. 2d 448, 454 (Fed. Cir. 1985).

² *Graham v. John Deere*, 838 U.S. 1, 17-18 (1965).

³ *KSR International v. Teleflex*, 127 S.Ct. 1727, 1736, 167 L.Ed.2d 705, 715 (2007) (emphasis added).

“obviousness under § 103 by inquiring into what the patentees (*i.e.* inventors) would have known or what would likely have done” at the time of invention.⁴ This is because:

The issue of obviousness is determined entirely with reference to a hypothetical “person having ordinary skill in the art.” It is only the hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor’s skill is irrelevant, and this is for a very important reason. The statutory emphasis is on a person of ordinary skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something – call it what you will – which sets them apart from the workers of ordinary skill⁵

Viewing obviousness from the vantage point of the inventor engages in impermissible hindsight.

That the inventors were ultimately successful is irrelevant to whether one of ordinary skill in the art, at the time the invention was made, would have reasonably expected success. . . . The court’s finding to the contrary represents impermissible use of hindsight – using the inventors’ success as evidence that the success would have been expected.⁶

Likewise, the expectations of the inventor, as stated in the patent disclosure, are irrelevant because that substitutes the subjective beliefs of the inventor for the objective belief of one of ordinary skill in the art prior to the invention.⁷ As reaffirmed in the recent *KSR* decision, the test for obviousness is defined by the *Graham* factors which focus on the prior art.

This is not to say that Dr. Lin may not testify at all about the inventive process in this trial. Rather, it is error for Roche to elicit testimony about Dr. Lin’s subjective expectations, beliefs and skill, and to attempt to bring those into the objective analysis of one of ordinary skill

⁴ *Standard Oil*, 774 F.2d at 454.

⁵ *Id.* at 454.

⁶ *Life Technol. v. Clontech Lab. Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000); see *Thomas & Betts Corp. v. ETC, Inc.*, 187 U.S.P.Q. 553, 570-71 (N.D. Ohio 1975) (evidence of the ease with which the inventor made the invention cannot be used to show obviousness).

⁷ *Noelle v. Lederman*, 355 F.3d 1343, 1353 (Fed. Cir. 2004) (expectation of success must be found in the prior art, not in the patent disclosure); *In re Dow Chemical*, 836 F.2d 469, 473 (Fed. Cir. 1988) (expectation of success must be found in the prior art, not in the patent disclosure). This requirement was not changed by *KSR*, but effectively reaffirmed through the Supreme Court’s affirmance of the *Graham* factors.

in the art. Such testimony is legally irrelevant under Rule 402, and is likely to lead to juror confusion under Rule 403.

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Respectfully Submitted,

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