

**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

**PLAINTIFF AMGEN INC.’S BRIEF IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 24
TO PRECLUDE EVIDENCE FOR OBVIOUSNESS THAT VIOLATES 35 U.S.C § 103
PROHIBITION THAT “PATENTABILITY SHALL NOT BE NEGATIVED BY THE
MANNER IN WHICH THE INVENTION WAS MADE”AND WHICH REFLECTS THE
SUBJECTIVE BELIEFS OF THE INVENTOR**

I. INTRODUCTION

In citing Dr. Lin's testimony about his expectations of success and how he reduced his inventions to practice, Roche seeks to elicit legally irrelevant testimony. An inventor's view of expectation of success in achieving the invention is not relevant to a determination of whether the invention is obvious to a person of ordinary skill in the art. Moreover, 35 U.S.C. §103(a) states: "Patentability shall not be negated by the manner in which the invention was made." Consequently, the facts of how an inventor conceived and reduced to practice the claimed invention is legally irrelevant to the obviousness inquiry.

Roche is seeking to use Dr. Lin's statements on his invention, how it was made, and statements Amgen made on its reduction to practice before the Patent and Trademark Office, to negative Dr. Lin's inventions under obviousness. Such use takes the subjective beliefs of the inventor, and all that the reduction to practice of the invention subsequently teaches, and uses it to render obvious that what the inventor conceived. These uses are impermissible because they seek (1) to substitute the subjective beliefs of the inventor for the objective belief of one of ordinary skill in the art prior to the invention, and (2) to use the acts of reduction to practice that occur after the invention (conception) to negative the invention (conception) that is reflected in the patent's claims. Accordingly, Amgen requests that such evidence be excluded under 35 U.S.C. § 103 and Federal Rule of Evidence 402 and 403.

II. THE SUBJECTIVE BELIEFS OF THE INVENTOR ARE IRRELEVANT TO PROVE OBVIOUSNESS

In support of its obviousness attack, Roche has identified statements made by Dr. Lin as to his subjective beliefs. For example, Roche's expert Dr. Lowe relies upon Dr. Lin's testimony as evidence to show obviousness:

Q: My question was, whether you had the expectation when you had the genomic EPO gene that when put into a mammalian cell and expressed, that the resulting EPO would be biologically active?

A: Of course, we would expect that it – to – to have that activity – in the biological activity¹

Dr. Lowe’s report is replete with statements by Dr. Lin about his invention to support his obviousness opinion.² Such use is impermissible.

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.³ Thus, it is improper to determine “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. This is because “[i]nventors, 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 part from the workers of ordinary skill. . . .”⁴ By contrast, obviousness must be evaluated not “through the eyes of the inventor, who may have been of exceptional skill . . .” or insight, but rather objectively through the eyes of the person of ordinary skill and may not use hindsight.⁵

Statements by Dr. Lin as to what he would have done and what he expected is plainly inadmissible under these authorities and should be excluded.

III. THE EVIDENCE OF HOW THE INVENTION WAS MADE IS IRRELEVANT TO OBVIOUSNESS

Likewise, Roche further seeks to bring inadmissible evidence of how the invention was made into the obviousness analysis. 35 U.S.C. Section 103(a) prohibits proving obviousness “**by the manner in which the invention was made.**”⁶ This sound prohibition against using the inventor’s inventive process to prove obviousness exists because it prevents the use of hindsight in the obviousness inquiry.

Roche attempts to use Amgen statements made during the interference between Genetics Institute (Fritsch) and Amgen (Lin) and testimony by Amgen employees on their work for Dr.

¹ Expert Report of Dr. Lowe, p. 53 (Gaede Decl., Ex. 1.)

² Expert Report of Dr. Lowe, pp. 37, 50-53, 105-108 (Gaede Decl., Ex. 1.)

³ See *Standard Oil Co., v. American Cyanamid Co.*, 774 F. 2d 448, 454 (Fed. Cir. 1985).

⁴ *Id.*

⁵ *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

⁶ 35 U.S.C. §103(a) (emphasis added).

Lin on reducing the invention to practice to show obviousness. Dr. Lowe's report is replete with testimony from Dr. Lin and Amgen employees on their work in reducing the inventions to practice to support an attack on obviousness. For example, Dr. Lowe's report states:

Indeed, in his testimony, Dr. Lin stressed just how obvious was the work in Example 7:

Q. Now, did you tell Dr. Browne's group how to do the work that's in example 7?

A. They already know how to do it. Any molecular biology – have given a piece of DNA and one to put into a vector, they know what they need to do. My associate can do it. They not even require a scientist to do it.

Q. Okay.

A. So, I mean, in general, all molecular biology know how to handle all these – all these things, yeah.

(Gaede Declaration, Ex. 1 at p. 50.)

Compounding this error, Roche seeks to bring before the jury a 1991 Board of Patent Appeals decision that addressed the issue of whether the work by Amgen employees in reducing the invention to practice constituted an inventive contribution under 35 U.S.C. § 102(f).⁷ The Board rejected the junior party's argument (Fritsch), finding that Dr. Lin did not need to be personally involved in all steps to be the sole inventor:

The record indicates that all the work at Amgen relating to expression of the EPO gene in mammalian host cells was directed and supervised by Dr. Browne, assisted by Ralph Smalling. Dr. Lin does not recall giving any instructions or suggestions as to how such expression should be carried out (PF V-3, 4). The effort to isolate the EPO glycoprotein expression product was carried out by Dr. Strickland, and Dr. Lin gave no specific instructions for accomplishing that task (PF V-6). However, the expression of the EPO genes in the mammalian host cells using the DNA sequence

⁷ Interference No. 102,097 ("the '097 Interference") was one of three separate interference proceedings instituted by the PTO, at the urging of Amgen's competitor, Genetics Institute, Inc. ("GI"), to determine priority as between Lin/Amgen and Fritsch/GI to various EPO-related inventions. The '097 Interference was declared on May 9, 1989. The "Process Count" of the '097 Interference was identical to claim 65 in Amgen's then-pending Application No. 07/113,179 ("the '179 application"). The '179 application later issued as U.S. Patent No. 5,441,868 ("the '868 patent").

isolated by Dr. Lin was carried out by Lin's request and on his behalf.

Lin argues that it is not essential for the inventor to be personally involved in carrying out process steps defined by the count where implementation of those steps does not require the exercise of inventive skill. We agree with Lin.

(December 3, 1991, Final Judgment, 21 U.S.P.Q.2d 1731 (Board of Patent Appeals).)

Roche now seeks to twist these statements on invention and reduction to practice into alleged admissions of obviousness. However, viewing obviousness from the vantage point of the invention 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.⁸

And it makes no difference whether the inventor is one who “innovate[s], whether by patient, and often expensive, systematic research or by extraordinary insights. . . .”⁹ In either case, it is evidence of how the invention was made and that is irrelevant to obviousness.

Moreover, isolating on individual steps performed during the inventive process to show obviousness violates the central obviousness inquiry: Obviousness must look at the claim as a whole and be compared to the prior art as a whole.¹⁰ It is impermissible to take individual steps from how the invention was made and then use these to negative the invention itself.¹¹

Roche's arguments also run afoul of 35 U.S.C. § 103(c) in that subject matter which qualifies only as prior art under 102(f) – Roche's argument that other workers at Amgen were the inventors of one or more steps of the process claims – is not properly considered for obviousness

⁸ *Life Technol. v. Clontech Lab. Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000); see also *Thomas & Betts Corp. v. ETC, Inc.*, 187 U.S.P.Q. 553, 570-71 (N.D.OH. 1975) (evidence of the ease with which the inventor made the invention cannot be used to show obviousness).

⁹ *Id.*

¹⁰ See *Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (“In determining obviousness, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed.”).

¹¹ 35 U.S.C. § 103(a).

where the inventions were owned by the same entity or subject to assignment to the same entity. Consequently, Roche's attempt to argue that Lin's inventions were obvious cannot be based on the fact that Browne or Smalling were involved in the expression work. Nor is this evidence relevant to a determination of obviousness, and it should be excluded.

To prove obviousness, Roche is impermissibly attempting to use individual steps performed by Dr. Lin and his co-workers in making the invention, and statements before the Board of Patent Appeals and Interferences on the invention. Such uses violate 35 U.S.C. § 103(a) and (c) and engage in the erroneous analysis of falling "victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."¹²

IV. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that this Court grant it's motion in limine and prohibit Roche from introducing as evidence of obviousness Amgen's statements describing how Dr. Lin's inventions were conceived and reduced to practice.

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Respectfully Submitted,

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¹² *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 1554 (Fed. Cir. 1983).

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