

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
)	Civil Action No.: 1:05-CV-12237 WGY
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.)	

**AMGEN’S BENCH MEMORANDUM REGARDING
ITS PROPOSED JURY INSTRUCTION ON OBVIOUSNESS**

Amgen requests this Court provide its revised jury instruction on obviousness as submitted in Amgen’s [Proposed] Revised Final Jury Instructions at XIV.K, filed herewith and said instruction attached hereto at Attachment A. The proposed instruction is based on the instruction that the Court has given in other cases, but contains a number of material additions necessitated by Roche’s improper attempt to have the jury engage in an improper obviousness analysis.

First, Roche argued in briefs and at bar that Dr. Lin’s subjective beliefs, his motivation and expectation of success, are relevant to a determination of obviousness.¹ In particular, Roche argued that the Supreme Court in *KSR Int’l Co. v. Teleflex, Inc.*² found that “in determining the obviousness of an invention and the reasonable expectation of success that a person of ordinary

¹ Roche’s Opposition to Amgen’s Motion *in Limine* No. 24 (D.I. 1001).

² 127 S.Ct. 1727, 1742 (2007).

skill in the art may have, the inventor’s own motivation and expectation of success is one of those factors.”³ ***It did not.*** To the contrary, in *KSR* the Supreme Court held that:

In determining whether the subject matter of a patent claim is obvious, ***neither the particular motivation nor the avowed purpose of the patentee controls.*** What matters is the ***objective*** reach of the claim.”

* * *

The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art.

Roche’s interpretation of *KSR* is diametrically opposed to the Supreme Court’s determination that an inventor’s subjective beliefs have no place in an obviousness inquiry. As Amgen pointed out in its Motion *in Limine* No. 24, an inventor’s skill and his subjective beliefs that make up the act of conception are irrelevant to obviousness.⁴ 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

Second, the instruction accurately focuses on the objective reasonable expectation of success. The question is what one of ordinary skill in the art would objectively expect to achieve based on the art available; what that fictional person’s reasonable expectation of success would have been at the time of the invention.⁶ The proposed instruction includes language to this effect that is in accord with two post *KSR* decisions.⁷ The proposed instructions also serve to remind the jury to avoid using hindsight in determining obviousness.

³ *Id.* at 4.

⁴ See *Standard Oil Co., v. American Cyanamid Co.*, 774 F. 2d 448, 454 (Fed. Cir. 1985) (“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 part from the workers of ordinary skill*** . . .”) (emphasis added).

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

⁶ See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *Takeda Chemical Indus. v. Alphapharm Pty.*, 492 F.3d 1350, 1360-63 (Fed. Cir. 2007).

⁷ *PharmaStem*, 491 F.3d at 1364.

Third, Amgen requests that the Court provide the jury with the proposed instruction relating to how the inventions were made and the work of other Amgen scientists in carrying out certain steps of the process claims as not relevant. Testimony elicited by Roche from Amgen witnesses and Roche's experts indicates that Roche will argue to the jury that the work of Dr. Lin and other Amgen employees in reducing Dr. Lin's inventions to practice is evidence that the inventions were obvious. Such argument is impermissible under 35 U.S.C. § 103(a) and (c).

The path that leads an inventor to the invention is expressly made *irrelevant* to patentability by 35 U.S.C. §103(a), which states that “[p]atentability shall not be negated by the manner in which the invention was made.”⁸ It is immaterial whether Dr. Lin's inventions resulted from long toil and experimentation or from a flash of genius.⁹ The inquiry for the jury is whether the relevant prior art would have rendered the claimed inventions obvious to one of ordinary skill in the art.¹⁰

Likewise, Roche presented testimony from other Amgen scientists, both live and by deposition, regarding their work in expressing, isolating, and testing Dr. Lin's recombinant human erythropoietin. Based on this testimony Roche is expected to argue to the jury that other Amgen scientists were the inventors of one or more steps of the process claims under 35 U.S.C. 102(f). The work of other Amgen scientists shall not preclude patentability – cannot render a patent obvious – where all of the subject matter was owned by or subject to assignment to Amgen.¹¹ Despite this law, the jury may be confused with respect to its evaluation of the work of others at Amgen in carrying out the work necessary to reduce to practice Lin's inventions.

Fourth, given that there was no clear path, the instruction addresses the language of KSR, which states: When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, *a person of ordinary skill* has good reason to

⁸ See *Life Technol, Inc. v. Clontech Technol, Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000).

⁹ 35 U.S.C. § 103 Revision Notes and Legislative Reports, 1952 Notes.

¹⁰ See *Life Technol.*, 224 F.3d at 1325.

¹¹ 35 U.S.C. § 103(c).

pursue the known options within his or her technical grasp.¹² There is no evidence in this record of a number of identifiable and predictable paths. Indeed, such a finding would be contrary to the Federal Circuit's decision in *Amgen v. Chugai*.¹³ "What cannot be contemplated or conceived cannot be obvious."¹⁴ Conception is a matter of law. The *Amgen* court held that conception of the EPO DNA sequence structure could not have occurred until Dr. Lin isolated the gene itself in October 1983. This *Amgen* matter of law holding is binding on the parties on principles of *stare decisis*. As a matter of law, since the EPO gene could not be conceived until Dr. Lin isolated it (an undisputed fact), it cannot be obvious and thus there could not have been a number of predictable solutions.

Based on the foregoing, along with the authorities cited in Amgen's instruction on obviousness, Amgen requests that its proposed jury instruction on obviousness be given.

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Respectfully Submitted,

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¹² *KSR*. at 1741-1742 (emphasis added).

¹³ *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991)

¹⁴ *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)

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I hereby certify that this document filed through the Electronic Case Filing (ECF) system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

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