

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05 CV 12237 WGY
)	
F. HOFFMANN-LAROCHE LTD.,)	
a Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LAROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**AMGEN’S RESPONSE TO ROCHE’S BENCH MEMORANDUM REQUESTING JURY
INSTRUCTION REGARDING AMGEN’S “FAILURE TO PROFFER SECONDARY
CONSIDERATION EVIDENCE OF THE FAILURE OF OTHERS SIMILARLY
SITUATED TO THE INVENTOR”**

Roche’s request for a jury instruction that Amgen must prove that each prior-art failure was made by a person who had all of Dr. Lin’s resources¹ is neither supported by case law nor appropriate for this case. In contrast, Amgen’s proposed instruction regarding secondary considerations of non-obviousness, which objectively lists the relevant considerations,² is consistent with both this Court’s instruction in *Ethos Technol., Inc. v. Realnetworks, Inc.*, Civil Action No. 02- 11324-WGY (D. Mass) (Young, C.J.) and the Federal Circuit Bar Association Model Patent Jury Instructions. Consequently, Roche’s request should be denied and the Court should provide Amgen’s proposed instruction to the jury.

¹ Roche Memo (D.I. 1363) at pp. 1-2.

² Amgen Inc.’s [Proposed] Revised Final Jury Instructions (D.I. 1318) at p. 44.

I. ARGUMENT

A. Roche's "similarly situated as Dr. Lin" instruction is flawed as a matter of law

In its nearly twenty-five years of jurisprudence, the Federal Circuit has never stated (even in *dicta*) that a patentee must show that a failed attempt to achieve the invention was by a person with the same resources, or otherwise "similarly situated," to the inventor. Indeed, the Federal Circuit has stated that all secondary considerations of non-obviousness "must always be considered, and given whatever weight is warranted by the evidence presented."³ That is, counsel may argue as to the weight of the evidence of failed attempts to make the invention, but an instruction is not appropriate.

Roche's desperation to undermine Amgen's evidence of secondary considerations of non-obviousness is apparent from its citation of inapposite case law. The district court opinions Roche cites do not support Roche's proposed instruction. Roche cites *Indecor v. Fox-Wells & Co., Inc.*, 642 F. Supp. 1473 (S.D.N.Y. 1986),⁴ but that case did not involve failed attempts by others as a secondary consideration. In *Indecor*, the patentee only offered evidence of

³ *Knoll Pharmaceutical Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004); *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed. Cir. 1984) ("The objective evidence of non-obviousness . . . may be the most pertinent, probative, and revealing evidence available to aid in reaching a conclusion on the obvious/nonobvious issue. It should when present always be considered as an integral part of the analysis."); *see also Ruiz v. AB Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000) ("Our precedents clearly hold that secondary considerations, when present, must be considered in determining obviousness."); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985) ("Just as it is legal error for a district court to fail to consider relevant evidence going to secondary considerations, it may be legal error for a district court to presuppose that all evidence relating to secondary considerations, when considered with the other *Graham* indicia relating to the obviousness/nonobviousness issue, cannot be of sufficient probative value to elevate the subject matter of the claimed invention to the level of patentable invention.").

⁴ Roche Memo (D.I. 1363) at pp. 1-2.

commercial success and a long-felt but unmet need for the invention.⁵ Consequently, the passage Roche quotes was not the holding in the case; it was merely *dicta*. Not surprisingly, *Indecor* has never been cited for this “similarly situated” *dicta* in the 20 years since it was published. Viewed in this context, the “similarly situated” language Roche borrows from *Indecor* cannot support Roche’s proposed instruction.⁶

Likewise, Roche’s reliance on *Carl Schenck, A.G. v. Nortron Corp.*, 570 F. Supp. 810 (M.D. Tenn. 1982), is without merit. In *Carl Schenck*, the patentee utilized a “hard-bearing” machine, available in the art since 1926, to solve a problem regarding the accuracy of the “soft-bearing” machines used to balance automobile tires.⁷ But the inventor was the first to successfully use the “hard-bearing” machine to solve the tire-balancing problem⁸ and the court found the invention non-obvious.

As in *Indecor*, the Court in *Carl Schenck* did not rely on the failed attempts of others as a secondary consideration of non-obviousness. Instead, the court relied solely on the commercial

⁵ *Indecor*, 642 F. Supp. at 1489 (“The evidence also shows that there were long perceived and unsolved problems in the art and that the patented product enjoyed commercial success.”).

⁶ Roche indicates that the *Indecor* court cited *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), and *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1574-75 (Fed. Cir. 1984), *cert. denied*, 471 U.S. 1065 (1985), as support for its “similarly situated” *dicta*. It did not. Neither of these cases held that failed attempts must be by others “similarly situated” to the inventor. The *Indecor* court cited these cases in support of the two other secondary considerations (“commercial success of the patented subject matter, [and] a ‘long felt but unsolved need []’ for the patented subject matter”) addressed in the same sentence from which Roche draws its “similarly situated” quote.

⁷ *Carl Schenck*, 570 F. Supp. at 811-12.

⁸ *Id.* at 814 (“Hard-bearing machines were known in the art since 1926 when one form was described in U.S. Patent 1599922 and the relative ease of measurement on such a machine was apparent long before the 1960's. Yet prior to the plaintiff's invention, no hard-bearing machine had achieved commercial success.”).

success of the patented product.⁹ Roche again relies on *dicta* that was irrelevant to the issues before the district court. If anything, the **holding** in *Carl Schenck* tends to support a conclusion of non-obviousness here: it cannot be disputed that Dr. Goldwasser's method for obtaining purified urinary EPO was available to the public for 6 years prior to Dr. Lin's cloning of the EPO gene.¹⁰

Roche's proposed "similarly situated" instruction is not supported by the cases it cites, and consequently, should not be submitted to the jury.

B. Roche's instruction is not appropriate in view of the evidence before the jury

Roche premises its request for a "similarly situated" instruction on its assertion that Amgen offered evidence of only one failed attempt by another to make Dr. Lin's inventions — the failure of Dr. Stuart Orkin.¹¹ That is incorrect. Roche ignores the numerous other failures that have been presented to the jury, in particular the failure of others to treat the anemia associated with chronic kidney disease. Drs. Friedman and Baron, and even Roche's own witness Dr. Spinowitz testified that Dr. Essers, Dr. Goldwasser, and others all attempted and failed to increase hematocrit or solve the major problem of the anemia of chronic renal failure.¹²

⁹ *Id.*

¹⁰ See Trial Exhibit 1, the '933 Patent, at 7:10-17; Trial Tr. 179:17-20 (Dr. Lowe) ("He [Goldwasser] has a publication in 1977 describing the purification of human urinary erythropoietin."); Trial Tr. 585:17-21 (Dr. Goldwasser) ("Q. When you published this paper in 1977, what was it you described? A. We described the method, consisting of seven discrete steps, in purifying human erythropoietin . . .").

¹¹ Roche Memorandum (D.I. 1363) at p. 1 ("For this issue, Amgen only presented evidence through Dr. Orkin and his failure to develop the claimed invention.")

¹² 9/12/07 Trial Tr. 889:12-890:22, 930:17-931:10, 945:23-946:2 (Spinowitz); Trial Tr. 2011:6-12 (Goldwasser) 9/25/07 Trial Tr. 1442:18-22 (Friedman), 9/26/07 Trial Tr. 1492:21-1493:2, 1496:6-24 (Friedman); 9/11/07 Trial Tr. 668:23-669:4 (Baron); see also TX 20, at p. 5 (Noting that until clinical trials with recombinant human EPO, it was not known whether EPO preparations could correct the anemia of patients with Chronic Renal Failure.)

Moreover, with regard to failed attempts to clone the human EPO gene, Roche argues that only Dr. Lin had access to Dr. Goldwasser's urinary EPO, and thus that nobody could have been "similarly situated as Dr. Lin." This ignores the testimony from Dr. Goldwasser that his method for purifying urinary EPO was known as early as 1977.¹³

Roche's "similarly situated as Dr. Lin" instruction should be rejected as an improper effort to prevent Amgen from relying on any failed prior-art attempt to make Dr. Lin's inventions.

C. The Court should adopt Amgen's instruction regarding secondary considerations of non-obviousness

Roche's proposed instruction is not supported by the case law and is inconsistent with the evidence in this case. In contrast, Amgen proposes an instruction similar to this Court's instruction in *Ethos Technol., Inc. v. Realnetworks, Inc.*, Civil Action No. 02- 11324-WGY (D. Mass.) (Young, C.J.), as well as the Federal Circuit Bar Association Model Patent Jury Instructions, which simply lists the various secondary considerations of non-obviousness.¹⁴

Amgen proposes the following instruction regarding "failed attempts of others":

In reaching your decision you should consider . . . 3) evidence that others tried but failed to accomplish the result achieved by the invention;¹⁵

II. CONCLUSION

Amgen requests that the Court reject Roche's proposed jury instruction because it is not supported by case law and is not appropriate for the facts in this case. Amgen requests that the Court instead adopt Amgen's proposed instruction because it is consistent with the case law,

¹³ See fn. 11 *supra*.

¹⁴ Amgen Inc.'s [Proposed] Revised Final Jury Instructions (D.I. 1318) at p. 44.

¹⁵ *Id.*

including this Court's instruction in *Ethos Technol., Inc. v. Realnetworks, Inc.*, and appropriate for the facts in this case.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on October 15, 2007.

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