

Keywords: Inequitable Conduct; Prophetic Examples; Past Tense; Present Tense; Misrepresentation; Intent; Materiality

General: Inequitable conduct was found based upon the presentation of an example in the past tense when the example had never been performed as written. The court found that the misrepresentation was made with an intent to deceive and was material to patentability, despite the failure of the claims to recite the misrepresented subject matter.

Hoffman-La Roche Inc. v. Promega Corp.
66 U.S.P.Q.2d 1385 (Fed. Cir. 2003)
March 31, 2003

I. Facts

On June 17, 1987, Cetus Corporation filed a patent application for a purified thermostable enzyme. The enzyme was a DNA polymerase found in the *Thermus aquaticus* bacterium and, therefore, known as the Taq polymerase. Because of its stability at high temperatures, the Taq polymerase is commercially valuable in a process known as the polymerase chain reaction, or PCR, which allows selected DNA sequences to be copied or amplified. The ability to amplify selected regions of small quantities of a DNA sequence is of great economic and scientific value.

During prosecution, the Examiner the submitted claims based on anticipation and obviousness in view of journal articles by Chien, et al. and Kaledin et al., both of which disclosed a Taq polymerase. In response, the Applicants cancelled the pending claims and entered three new claims that were differentiated from the cited art based on the molecular weight of the claimed Taq polymerase.

Though the new claims recited molecular weight limitations, the Applicants included remarks discussing how the claimed Taq polymerase was also differentiated by its specific activity and fidelity. In the alternative, the Applicants argued that, even if the claimed Taq polymerase was the same as the cited Taq polymerase, it was still distinguishable due to its purity. The examiner allowed the new claims without comment and the claims issued in U.S. Patent No. 4,889,818 (the '818 patent).

Cetus licensed the '818 patent to Promega Corporation. Cetus subsequently sold the '818 patent to Roche. After the transfer of the patent, Promega allegedly breached the licensing agreement, prompting Roche to file suit alleging patent infringement and breach of contract. Promega counterclaimed alleging, *inter alia*, that the '818 patent was unenforceable due to inequitable conduct.

The district court held on summary judgment and after a bench trial that the patent was unenforceable due to eight separate misrepresentations and omissions made by the inventors. Roche appeals from this decision.

II. Issues

- A. Did the district court err in finding inequitable conduct in the inventors' omissions regarding the molecular weight of the reference Taq polymerases?

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- B. Did the district court err in finding misrepresentation in the inventor's presentation of Example VI?
 - C. Did the district court err in finding intent to deceive the PTO in the inventor's presentation of Example VI?
 - D. Did the district court err in finding materiality in the inventor's presentation of Example VI?

III. Discussion

- A. Yes. Inequitable conduct requires a misrepresentation or omission of a material fact along with an intent to deceive, both of which must be shown by clear and convincing evidence. The Federal Circuit found that critical differences existed in the experimental conditions by which the inventors and the authors of the Chien reference determined molecular weight. As a result, the district court improperly concluded that the inventors' experiment was material. Similarly, the Federal Circuit found that there was no intent to deceive associated with the inventors' failure to disclose their experimental results to the Patent Office.
- B. No. The majority placed great weight on the use of the past tense in presenting Example VI when the inventor's had not performed all of the steps of Example VI *at one time* or *in the recited order*, i.e., as written. Similarly, since Example VI was never performed as written, the stated result was never obtained. In particular, the majority found that the use of the past tense precluded any representation of Example VI as a prophetic example. Furthermore, the district court did not clearly err in finding misrepresentations in Example VI in the asserted achievement of "single-band purity," "a nuclease-free preparation," and the asserted specific activity. To the extent that the inventors had failed to obtain these stated results in other experiments, including the ones presumably combined into Example VI, the inventors were found to have made a misrepresentation.
- C. No. Testimony from at least one inventor indicated that he understood the significance of using the past tense, at least in scientific publications. Roche failed to establish, via the inventor's testimony or other evidence, that a different standard should apply in a patent application or why the past tense would be used to describe an experiment that was not performed. Furthermore, the district court's finding that the inventor's had a good faith belief that they had discovered a different Taq polymerase was not incompatible with a finding of intent to deceive. Therefore the district court did not err in finding intent.
- D. No. *Materiality is not limited to the subject matter of the claims.* Information is material when there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue. The inventors made representations during prosecution as to the purity of the claimed Taq polymerase relative to the Taq polymerase in the art. The purity representations were made in the form of an alternative argument for patentability made in anticipation of possible future amendments. Nevertheless, the fact that the examiner did not rely on the purity representations in issuing the patent is *not* inconsistent the representations being material. The district court, therefore, did not clearly err.

IV. Conclusion

The district court failed to determine whether the material misrepresentations were sufficiently serious, under all the circumstances, to justify holding the patent unenforceable. Due to this failure and because the majority did not uphold all of the grounds for inequitable conduct, the majority vacated the order of unenforceability and remanded the case to the district court.

The dissent concurs with the majority with regard to the reversal in regard to the issue of molecular weight but dissents from the remainder of the opinion. With regard to Example VI, the dissent takes issue with the majority's focus on the past tense presentation, particularly because patentability does not depend on whether an example has actually been conducted.

In prosecution practice, this case provides a number of lessons. Do not make arguments or comments in a response that are outside the scope of the claim recitations. Do not use absolute terminology, i.e., single-band or *x*-free, unless necessary or unequivocally true. Here, for example, *main*-band or *substantially* free of *x* may have improved the tactical situation. Be conscious of the use of past and present tense, particularly in examples. Be careful in your characterization of the prior art, particularly when different experimental methodologies were employed.