

Hoffmann-La Roche, Inc. v. Promega Corp., No. 00-1372
(U.S. Court of Appeals for the Federal Circuit, Fed. Cir. Mar. 31, 2003)

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Summary

The U.S. Court of Appeals for the Federal Circuit addressed the issue of inequitable conduct during patent prosecution. Upon affirming the majority of a district court's findings of inequitable conduct, it remanded the case for a determination of whether the incidents of inequitable conduct justified the sanction of rendering the patent unenforceable.

The Facts

The dispute¹ revolved around U.S. patent No. 4,889,818 (hereinafter 'the '818 patent'), titled "Purified Thermostable Enzyme" and owned by Hoffmann-La Roche, Inc., and Roche Molecular Systems, Inc. (hereinafter 'Roche'). The patent concerned DNA polymerase isolated from the *Thermus aquaticus* (hereinafter 'Taq') bacterium. The patent was first issued to Cetus Corporation in 1989. During patent prosecution, the United States Patent and Trademark Office (hereinafter 'USPTO') rejected the original patent application for obviousness, citing two journal articles. Cetus amended its application by cancelling all pending claims and adding three new ones, emphasizing differences in molecular weight, specific activity, and fidelity of the Taq enzyme. Cetus argued in particular that the claimed enzyme was "far more pure" than the one in the prior art. The USPTO ultimately granted Cetus' application, issued as the '818 patent in 1989. The patent included ten examples illustrating the scope of the invention.

In 1990, Cetus licensed the '818 patent to Promega Corporation (hereinafter 'Promega') and shortly after, sold the rights to the patent to Roche. In 1992, Roche sued Promega for breach of contract and patent infringement. Promega in return raised inequitable conduct as a counterclaim. In 1999, a district court ruled in favour of Promega, finding the '818 patent unenforceable due to inequitable conduct during the prosecution of the patent on the basis of various misstatements about Taq. Roche appealed to the U.S. Court of Appeals for the Federal Circuit (hereinafter 'the Federal Circuit').

The Legal issues

The Federal Circuit stated that a successful defense of inequitable conduct must demonstrate, by clear and convincing evidence, "misrepresentation or omission of a material fact, together with an intent to deceive the [USPTO]". If those two elements are satisfied, the court must then "determine whether the equities warrant a conclusion that the patentee has engaged in inequitable conduct". The Federal Circuit subsequently analyzed the various misstatements found by the district court and grouped them into the three following categories:

“(1) representations regarding the difference in molecular weight between the claimed and prior art Taq enzymes;

¹ Hoffmann-La Roche, Inc. v. Promega Corp., No. 00-1372 (Fed. Cir. Mar. 31, 2003).

- (2) representations that the inventors had performed Example VI, one of the procedures described in the specification, and that they had achieved the described results; and
- (3) representations concerning the comparative fidelity and template dependence of the claimed enzyme and the prior art enzymes.”

First, the Federal Circuit reviewed the category of misstatements relating to molecular weight. On summary judgment, the district court concluded that Cetus withheld material information during prosecution of the patent ‘818 regarding the disparity in the molecular weight values reported for the prior art enzymes and the claimed enzyme. It found that the ‘Stoffel experiment’, an undisclosed experiment conducted by Cetus, was suggesting that the prior art enzyme was not a degraded form of Taq. In the district court’s opinion, this finding called into question the reported weight difference between the prior art and the claimed enzymes. Likewise, the district court found that the inventors failed to disclose information which suggested that the molecular weight value in the prior art was likely underestimated, reducing thereby the difference in the molecular weight of the prior art and claimed enzymes.

The Federal Circuit disagreed. It noted that it was not clear whether the Stoffel experiment was relevant to the inventors’ characterization of the prior art enzyme and it found no evidence of intent to deceive the USPTO by failing to disclose the Stoffel experiment. The Federal Circuit neither found evidence indicating that the measurement of molecular weight value in the prior art was inaccurate and underestimated.

Second, the Federal Circuit analyzed the district court’s findings regarding Example VI, one of the ten examples described in the patent application to illustrate the scope of the ‘818 patent. The district court found that Example VI, a purification protocol of the claimed enzyme, had never been performed. Hence, the inventors never obtained the described results of Example VI. The district court held that the use of the past tense, on more than 75 occasions, to describe the steps of Example VI wrongfully suggested that the protocol had been performed. Moreover, the district court concluded that these misrepresentations were intentional. The court pointed out, *inter alia*, that the inventors attested that all statements made in the 818’ patent application were true. Additionally, the district court held that the inventors’ misrepresentations were material, as a reasonable examiner would have considered them important during the prosecution in deciding whether to grant a patent or not.

The Federal Circuit upheld the district court’s findings regarding Example VI, stating that none of these findings could be deemed clearly erroneous. The Federal Circuit held, among other things, that information is material when a reasonable examiner would like to have the information at issue while deciding whether to allow the application to issue. Therefore, the Court concluded that material information does not only include matters reflected in the claims of a patent. Additionally, the Federal Circuit held that “affirmative misrepresentations by the patentee [as was the case with respect to the issue of Example VI], in contrast to misleading omissions, are more likely to be regarded as material”.

The Federal Circuit finally examined the last category of misstatements related to the fidelity and template dependency of the claimed enzyme in comparison to the prior art enzymes. Even though the inventors’ statements about the fidelity of the claimed enzyme were correct, the

district court found that “the statements characterizing the activity of the prior art enzymes and comparing it to that of the claimed enzyme were inaccurate”. According to district court, the inventors alleged that the claimed enzyme showed greater fidelity and template dependence than the prior art enzymes in order to strengthen their argument for patentability - that their claimed enzyme was distinct from the enzyme of the prior art. Therefore, in the point of view of the district court, the inventors’ affirmative misrepresentations were material. Furthermore, the district court held, relying heavily on Promega’s expert witness, that the inventors intentionally sought to deceive the USPTO. In the view of the Federal Circuit, the district court’s determinations were not clearly erroneous. The Federal Circuit explained among other things that intention can be proved inferentially, as was the case here, and does not require the inventor’s or the prosecuting attorney’s confession. The Federal Circuit therefore upheld the district court’s findings on the fidelity issue.

Since the Federal Circuit did not uphold all of the grounds on which the district court found inequitable conduct, it vacated the district court’s unenforceability order and remanded the case so the district court could “determine, in the exercise of its judgment, whether under all the circumstances, the incidents of inequitable conduct [...] are such as to justify the sanction of rendering the ’818 patent unenforceable”.

In a strong dissent, Judge Newman, one of the three-judge panel, drew attention to the threat of a “new plague” of inequitable conduct allegations, considering the majority’s standard for proving inequitable conduct too low. While Judge Newman agreed with the majority’s decision with respect to the molecular weight, she would also have reversed all the other grounds on which the district court found inequitable conduct. Judge Newman accused the Federal Circuit’s judgment to distort “the patent process [...] into a game of high stakes hindsight that few patents can survive”. Such rulings, according to Judge Newman, create a climate of suspicion where “all scientists are knaves and all patent attorneys jackals”. To avoid such situations, Judge Newman underlined the importance of the ‘clear and convincing evidence’ requirement.

Points of Significance

- On remand, the district court held the ‘818 patent once again unenforceable for inequitable conduct².
- Under US law, inequitable conduct requires misrepresentation or omission of a material fact, together with intent to deceive the USPTO, which must be demonstrated by clear and convincing evidence. The Federal Circuit had already addressed this issue before, see *Merck & Co., Inc. v. Danbury Pharmacal, Inc. (1989)*.³
- The TRIPS Agreement contains no minimum standards on the material consequences of inequitable conduct by the patent applicant during patent prosecution.

² Hoffman-La Roche, Inc. v. Promega Corp., 319 F. Supp. 2d 1011, 1014–16 (N.D. Cal. 2004).

³ See the summary in this database.

Key words

Inequitable conduct, misrepresentation and omission of a material fact, intent to deceive, patent unenforceability

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