

Patent owners rejoice: Inequitable conduct in litigation more difficult to prove

Decision raises the threshold to prove inequitable conduct in patent litigation

The Federal Circuit's *en banc* decision in *Therasense v. Becton* raises the threshold for proving inequitable conduct as a defense to patent infringement. "To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO." The Federal Circuit explained that, to prove specific intent to deceive, requires an accused infringer must "prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."

Therasense (now Abbott) filed a patent application for disposable blood glucose test strips for diabetes management. During the 13 years of prosecution, the application received multiple rejections for anticipation and obviousness. To overcome these rejections, Abbott submitted an affidavit from its Director of Research and Development, and the application finally issued as U.S. Patent No. 5,820,551 (the '551 Patent).

Several years earlier, however, while prosecuting the corresponding European patent application, Abbott made certain representations to the European Patent Office that were inconsistent with the affidavit submitted in the U.S. application, and Abbott failed to provide the U.S. Patent and Trademark Office (PTO) with the arguments it had submitted in the corresponding European patent application.

Abbott sued Becton, Dickinson & Co. for infringement of the '551 Patent. During this action, the District Court held that the '551 Patent is unenforceable due to inequitable conduct because Abbott did not disclose to the PTO the arguments it submitted to the European Patent Office during the prosecution of its corresponding European patent application. On appeal, the Federal Circuit Court vacated the District Court's inequitable conduct judgment and remanded the case back to the District Court. But shortly thereafter, the entire Federal Circuit granted rehearing of the case by the entire court.

In its *en banc* decision, the Federal Circuit rejected the previous rule of a "sliding scale" approach where a weak showing of intent may nonetheless be sufficient based on a strong showing of materiality, and vice versa. Instead, the Federal Circuit held that intent to deceive must be determined independent of materiality. In reaching its decision, the Federal Circuit expressed concern that the low standards for intent and materiality currently applied has inadvertently led to many unintended consequences, such as "increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality."

Intent

The accused infringer must prove intent to deceive by clear and convincing evidence. The Federal Circuit held that intent may be inferred from indirect and circumstantial evidence: "The specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." If, however, there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. The Federal Circuit further stated that the absence of a good faith explanation of withholding a material reference does not by itself prove intent to deceive.

Materiality

The Federal Circuit held that the materiality required to establish inequitable conduct is but-for materiality: "When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." In making this determination, the preponderance of the evidence standard is applied and the claims given their broadest reasonable construction.



The Federal Circuit did find one exception to the above rule. When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material by definition.

In reaching its decision, the Court refused to adopt the definition of materiality in Patent Rule 56, stating that reliance on the Rule has led to the very problems the Federal Circuit is attempting to address. In response to the decision, the PTO posted a notice on its website that it will review the case and publish any impact it may have on practice before the PTO. This decision will likely result in modifications to Patent Rule 56 making it consistent with this decision by raising the standard for what constitutes material prior art.

One likely result of this decision is that patent practitioners may cite fewer references during prosecution of patent applications, which could ultimately result in a reduction in lead time for examination of applications. Moreover, this decision likely will result in fewer accused infringers claiming inequitable conduct by a patentee during prosecution of its patent, which could ultimately reduce the issues before the courts speeding up patent litigation cases. On the other hand, the new higher standard results in one less defense available to accused infringers. Only time will tell, however, how this decision impacts not only prosecution of patents, but how those patents are enforced and litigated.

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