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## Federal Circuit Clarifies Standard for Proving Inequitable Conduct in Patent Cases

by Ted J. Barthel and Christopher R. Walker

On May 25, 2011, the U.S. Court of Appeals for the Federal Circuit, on appeal from the U.S. District Court for the Northern District of California, issued its *en banc* decision in *Therasense, Inc. v. Becton, Dickinson and Co.*, No. 2008-1511 (hereafter *Therasense decision*). The Federal Circuit maintained the two-prong test for inequitable conduct—to prevail on a claim of inequitable conduct, the accused infringer must prove by clear and convincing evidence that: (1) the patentee acted with specific intent to deceive the Patent and Trademark Office (PTO), and (2) the information withheld is material to the patentability of a claim of the asserted patent. The *Therasense decision* clarifies the standards for finding both (1) intent and (2) materiality.

As background, the Court noted the inequitable conduct doctrine has become “a plague” upon the courts and the entire patent system. A finding of inequitable conduct to a single patent claim renders the entire patent unenforceable. With this far-reaching consequence, the party accused of patent infringement charges inequitable conduct in almost every patent litigation case. During the patent application process, patent prosecutors regularly bury PTO examiners with a deluge of prior art references out of concern over a future inequitable conduct charge. The Court observed that the doctrine of inequitable conduct has resulted in many

unintended consequences—including increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality.

In view of these unintended consequences, the *Therasense decision* tightens the standards for finding both intent and materiality in the inequitable conduct inquiry.

### Intent

The *Therasense decision* holds that in order to prove intent to deceive, the accused infringer must prove by clear and convincing evidence that the patentee knew of the reference, knew that it was material, and made a deliberate decision to withhold it. In clarifying the standard for proving intent, the Federal Circuit reaffirmed that materiality and intent are separate requirements and the Court rejected the current “sliding scale” approach where a weak showing of intent may be found sufficient based upon a strong showing of materiality, and vice versa. The Federal Circuit clarified that a court may not infer intent solely from materiality. However, a court may still infer intent from indirect and circumstantial evidence because direct evidence of deceptive intent is rare. To meet the clear and convincing evidence standard, the specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” The Court stated

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that when multiple reasonable inferences may be drawn, “intent to deceive cannot be found.” Thus, “the absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.”

### Materiality

The *Therasense decision* sets forth a new “but-for materiality” standard. Under the new standard, “prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” The Federal Circuit rejected the current materiality standard provided in 37 CFR §1.56 (Rule 56). The new but-for materiality standard is stricter than the Rule 56 materiality standard, with the new threshold now being whether the PTO would have allowed the claim had it been aware of the undisclosed reference. Even if the “but-for” standard is not met, the Court made clear that egregious cases of misconduct by a patentee (such as the filing of a false affidavit) may be punished.

### Comment

The *Therasense decision* raises the bar for asserting inequitable conduct by accused patent infringers. It remains to be seen whether the PTO will issue a formal statement regarding the new “but-for” materiality standard. Patent applicants should continue to meet their duty of disclosure by submitting the most relevant and known prior art to the PTO.

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