

## Federal Circuit Ratchets Up Materiality Requirement for Inequitable Conduct

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A deeply divided (6-1-4) Federal Circuit revised the materiality prong of the inequitable conduct defense, which permits a patent infringer to argue that an entire patent (as well as related patents and patent applications) should be declared unenforceable in light of the patentee's wrongful conduct during patent prosecution. This decision will likely please practitioners involved in patent prosecution as well as patent owners.

In a decision that will likely please practitioners involved in patent prosecution as well as patent owners, on May 25, 2011, a divided U.S. Court of Appeals for the Federal Circuit issued its ruling in the *Therasense* case, which the Federal Circuit took *en banc* to reconsider the legal standard for inequitable conduct. The doctrine of inequitable conduct allows a patent to be ruled unenforceable based on a finding of wrongdoing by the patentee if specific intent to deceive and materiality are both shown. Citing the rampant overuse and unintended consequences of the doctrine, the court imposed a new, heightened standard for materiality.

A deeply divided (6-1-4) Federal Circuit revised the materiality prong of the inequitable conduct defense, which permits a patent infringer to argue that an entire patent (as well as related patents and patent applications) should be declared unenforceable in light of the patentee's wrongful conduct during patent prosecution. Six judges joined in the entirety of the court's opinion. A seventh judge joined part of the court's opinion discussing intent and wrote a separate opinion concurring-in-part and dissenting-in-part as to the materiality standard. The remaining four judges dissented in a lengthy opinion. *Therasense, Inc. v. Becton Dickinson & Co.*, Case No. 2008-1511 (Fed. Cir. May 25, 2011) (*en banc*) (opinion for the court by Rader, C.J., joined by Judges Newman, Lourie, Linn, Moore and Reyna) (O'Malley, J., concurring-in-part and dissenting-in-part) (Dyson, J., dissenting, joined by Judges Gajarsa, Dyk and Prost).

In the trial court, the district judge found inequitable conduct based on failure to disclose to the U.S. Patent and Trademark Office (USPTO) that contradictory statements had been made in a different proceeding. The patent-in-suit is for test strips with an electrode and reactant system used to measure blood sugar in diabetic patients. Measurements of blood sugar can be made either from whole blood samples or from other types of samples. The issue involved whether a person of ordinary skill in the art would understand that an electrode system for use with whole blood must have a membrane to protect the electrode. According to an earlier patent, strips to test whole blood samples "optionally, but preferably" had a membrane. In European patent proceedings, the patent owner argued that the language "optionally, but preferably" meant a membrane was not required, *i.e.*, it was optional. In the USPTO, the patent owner submitted a sworn declaration and supporting argument stating that the language

“optionally, but preferably” in the earlier patent would be read by a person of ordinary skill to mean that a membrane was required, *i.e.*, it was not optional. The declaration submitted to the USPTO was in direct response to concerns expressed by the examiner. The patent owner never disclosed the statements that were made in the European proceeding to the USPTO. The trial court found specific intent to deceive the USPTO and that the contradictory statements were material, and ruled that the patent-in-suit was unenforceable.

## New “But For” Standard for Materiality

The Federal Circuit’s opinion vacated the inequitable conduct judgment and remanded to the trial court for further proceedings in accordance with the new standard. The Federal Circuit’s opinion affirms that the law of inequitable conduct relating to nondisclosure continues to require two separate showings: specific intent to deceive, and materiality. The burden of proof that the accused infringer must meet is still clear and convincing evidence.

As articulated by the majority, the intent requirement remains unchanged. Specifically, the proper standard for intentional nondisclosure is “knowing and deliberate,” although the majority concedes that some cases had incorrectly suggested that a negligence-type, “should have known” intent standard was sufficient. In the words of the court, the intent requirement requires “clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” When circumstantial evidence of intent is used, an intent to deceive must be the most reasonable inference.

It is the materiality standard that is radically changed. Prior to *Therasense*, the Federal Circuit had developed a materiality standard that was based on the USPTO’s Rule 56 which sets forth disclosure standards for lawyers and others involved in patent prosecution. The *Therasense* opinion jettisons that entire approach. The court specifically rejected the current version of Rule 56, which provides that information is “material” if it is noncumulative and “refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the [USPTO], or (2) asserting an argument of patentability.” The court explained that, among other things, this part of Rule 56 “sets such a low bar for materiality” that it encourages the existing and problematic practice of dumping prior art of marginal relevance on the USPTO during patent prosecution.

After *Therasense*, the legal standard for materiality is not tied to the USPTO Rule 56. Instead, where an applicant has failed to disclose prior art to the USPTO, the trial court will be required to determine whether the undisclosed art meets a “but for” materiality test, which requires that the USPTO would not have allowed a patent claim if it had been aware of the undisclosed prior art. To make that determination, the trial court is instructed to apply a preponderance of the evidence standard and give claims their broadest reasonable construction, *i.e.*, apply the evidentiary standards that the USPTO would have used to decide whether the prior art rendered the claim unpatentable. This is a completely different materiality analysis from the Rule 56-based inquiry that the district courts carried out under the

old standard. This is an appropriate standard, the court explained, because it looks to whether the patentee actually reaped an unfair benefit by its wrongful failure to disclose. Accordingly, on remand, the trial court must determine whether, in this case, the USPTO would have found the declaration and accompanying arguments unpersuasive in overcoming the pending obviousness rejection if the patent owner's representatives had disclosed the statements made in the European prosecution.

## Exceptions for Egregious Conduct

The court's opinion sets up an exception to the new "but for" standard in cases of "affirmative egregious conduct." The court recognized that the "but for" test would not, by itself, be adequate to capture all cases of egregious and abusive conduct. This exception, the court stated, incorporates elements of early "unclean hands" cases from the Supreme Court of the United States, which dealt with egregious misconduct. Using this exception, the majority believes it will achieve the necessary balance between encouraging honesty and curtailing the excessive use of the inequitable conduct defense, after referred to as a "plague." While the court used the specific example of a false affidavit to illustrate the exception, the court indicated the exception was not so limited, but rather is intended to ensure the materiality standard had sufficient flexibility to capture and punish unusually abusive conduct. The majority warned, however, that the exception is not meant to be a catch-all, and would not cover, for example, mere nondisclosure of prior art references. Nor does the provided exception contemplate a return to the "reasonable examiner" standard associated with Rule 56.

## The Majority's Rational

The Federal Circuit's *Therasense* opinion plainly states that this change in the law was made out of necessity to address "the problems created by the expansion and overuse of the inequitable conduct doctrine." Over time, the intent and materiality standards for proving inequitable conduct were lowered to encourage full disclosure to the USPTO. "This new focus on encouraging disclosure has had numerous unforeseen and unintended consequences." The inequitable conduct defense came to be raised in virtually every case, cabined only by the limits of attorney imagination to find "the slenderest grounds" to support a charge of inequitable conduct. The availability and overuse of this defense led to expanded discovery and increased litigation costs, discouraged settlement and diverted attention and resources from the merits of infringement and invalidity issues. "Perhaps most importantly, the remedy for inequitable conduct is the 'atomic bomb' of patent law," rendering whole patents, and in some cases, entire families of patents, unenforceable. "Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system." Faced with these realities, the Federal Circuit decided to make a major break with prior precedent to reign in the doctrine.

## Vigorous Dissent to Adoption of New Standard

There is deep disagreement within the court over the rule announced by the majority. The main group of four dissenters disagreed with the replacement of the Rule 56 standard. Those judges thought that long-standing precedent should not be overturned and they would have made more limited changes to the legal standards, including a tightening of the intent element. They argued that, in other areas of law, a “but for” standard of materiality has been largely rejected, and that it had been repeatedly rejected by the Federal Circuit itself in cases involving inequitable conduct. Moreover, in their view, it is critical that the courts should continue to look to Rule 56, which encompasses the USPTO’s considered view of what standard of conduct is needed and should govern the examination of patents. The dissenting group also expressed a belief that the higher standard for materiality will undermine the existing incentives to refrain from dishonesty before the USPTO. Indeed, they asserted, the “but for” test comes close to abolishing the doctrine of inequitable conduct altogether, since a finding of inequitable conduct will generally be made only after claims have been found invalid.

The other dissenter, Judge O’Malley agreed that the old Rule 56 standard was inadequate, “too vague and too broad.” On the other hand, Judge O’Malley objected that the new test was too narrow and too rigid. She supported a test that included the “but for” standard, but also deemed conduct to be material if it constitutes a false or misleading representation of fact, or was “so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined.” Judge O’Malley also suggested that the remedy for inequitable conduct should not be limited to ruling that a whole patent is unenforceable; rather, the courts should have discretion to fashion an appropriate remedy, in the exercise of their equitable powers.

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