



## Intellectual Property Alert

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JUNE 10, 2011

# In *Therasense*, the Federal Circuit Breathes Some Sense into Inequitable Conduct

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The Federal Circuit has made it substantially more difficult for an accused infringer to successfully assert a defense of inequitable conduct based upon the Patentee's failure to disclose information to the United States Patent and Trademark Office (USPTO or "the Office") during prosecution.

*Therasense, Inc. v. Becton, Dickinson & Co.* (Fed. Cir. May 25, 2011). Sitting *en banc*, the court noted that inequitable conduct had become "a plague" not only on the courts, where it was "routinely brought on the slenderest of grounds" by reputable attorneys against other reputable attorneys, but also on the "entire patent system." Slip op. at 23. Unlike the doctrine of unclean hands on which it was based, inequitable conduct had not been limited to egregious affirmative acts of misconduct intended to deceive the USPTO and the courts. Instead, it had been broadened to include even "the mere nondisclosure of information to the PTO." *Id.* at 19. The remedy, too, had become more drastic. Instead of the mere dismissal of the suit warranted by a finding of unclean hands, the remedy for inequitable conduct had become "the atomic bomb" of patent law—rendering the entire patent, and sometimes entire patent families, unenforceable. *Id.* at 21.

Under the new rule announced in *Therasense*, there must be proof that the patentee acted with *specific intent to deceive* the USPTO. *Id.* at 24 (emphasis added). A finding of gross negligence or negligence under a "should have known" standard is no longer enough. *Id.* Instead, it must be shown that the applicant knew of the reference, knew it was material to patentability, and made a *deliberate decision* to withhold it from the PTO. *Id.* (emphasis added). Although intent may be inferred from indirect and circumstantial evidence, a "specific intent to deceive *must be the single most reasonable inference* able to be drawn from the evidence." *Id.* (emphasis added). The evidence "must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." *Id.* at 26 (emphasis added). The court explained that "where there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* Moreover, the absence of a good faith explanation for withholding a material reference will not, by itself, be sufficient to prove intent under the rule in *Therasense*. No explanation is required unless the accused infringer first proves a threshold level of intent by clear and convincing evidence. *Id.*

The majority opinion also stressed that intent and materiality are separate and distinct requirements—there is no "sliding scale" where intent can be inferred from the degree of materiality. How relevant to patentability must a reference be for it to be considered "material"? The *Therasense* court held that the standard is one of "but-for" materiality, expressly declining to adopt the broad definition of materiality set forth in USPTO Rule 56. *Id.* at 27.

To prevail under the "but-for" standard established in *Therasense*, the accused infringer must show by a preponderance of the evidence that, had it been aware of the undisclosed prior art, the

USPTO would not have allowed a claim. *Id.* at 28. The Court explained that “inequitable conduct hinges on basic fairness” and that “the remedy... should be commensurate with the violation.” *Id.* Since a finding of inequitable conduct renders an entire patent, and even an entire family of patents, unenforceable, the doctrine should now be reserved only for “instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” *Id.* Where no such claim was granted, “the patentee obtains no advantage” and “enforcement of an otherwise valid patent does not injure the public merely because of misconduct lurking somewhere in patent prosecution that was immaterial to the patent’s issuance.” *Id.* at 29.

The one exception to proving “but-for” materiality is in cases of “affirmative egregious misconduct.” *Id.* at 29. The court explained that in cases where the patentee engages in misconduct such as filing a false affidavit, perjury, suppression of evidence, manufacture of evidence, and bribery, the misconduct itself is material. *Id.* at 30. But the failure to mention a prior art reference in an affidavit does not amount to egregious misconduct. *Id.*

In summary, the decision in *Therasense* makes it much more difficult to prove inequitable conduct based upon the mere nondisclosure of a reference to the USPTO during prosecution. The twin requirements of a specific intent to deceive and “but-for” materiality will likely reduce the perceived need to disclose large amounts of prior art that may have only marginal relevance to the claimed invention. In a May 26th press release, the USPTO announced that it is studying the impact of the *Therasense* decision on agency practices and procedures and will soon issue new guidelines regarding the information that must be disclosed to the Office. But the Federal Circuit’s decision may not be the end of the story. Becton, Dickinson and Company recently announced plans to ask for Supreme Court review, asserting that the “but-for” standard is inconsistent with precedent and alleging that the decision reduces a patent applicant’s incentive to comply with USPTO rules.

If the *Therasense* decision holds, and depending on the scope of any new guidelines, both patentees and applicants may soon benefit from a substantial reduction in both the risks and the costs associated with the duty of disclosure.

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1181-0611-NAT-IP