

Patent Law Update: Therasense v. Becton Dickinson

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Therasense on Patent Inequitable Conduct – The Decision of the Federal Circuit “Fixes” Inequitable Conduct Law

by Charles W. Shifley

May 25, 2011, the Federal Circuit issued the much awaited *en banc* (full court) decision about patent inequitable conduct in *Therasense, Inc. v. Becton, Dickinson & Co.* According to a dissent, the Court “comes close to abolishing [the doctrine of inequitable conduct] altogether.” Slip op. dissent at 5.

In a surprise decision, the Court majority narrowed the materiality test for inequitable conduct to “but-for materiality” — as a general matter. Explaining the application of the new rule to the important situation of undisclosed prior art, the Court stated, “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.” Slip op. at 27. Patent applicants thus have a different assurance in this standard than in the past as they go about considering whether to disclose what they judge to be marginal prior art.

The Court also narrowed the intent test, as well, to a tight recitation of the *Kingsdown*, *Star Scientific* and *Scanner Techs.* standards. Slip op. at 25. “[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be the ‘single most reasonable inference above to be drawn from the evidence.’” *Id.* Adding emphasis, the Court stated, “the evidence ‘must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.’” *Id.* “Hence,” it said, “when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” Slip op. at 26.

Moreover, the Court stated there is not to be a “sliding scale” balancing materiality and intent, and that intent may not be inferred solely from materiality. Slip op. at 25.

Thus, the Court’s six judge majority opinion (written by Chief Judge Rader, for himself and Judges Newman, Lourie, Linn, Moore and Reyna (appointed in 2011)) represents the Court’s abandonment of the “reasonable examiner” standard of materiality, the gross negligence standard of intent, and the balancing of materiality and intent. It also represents the Court’s rejection of current “Rule 56” (37 CFR 1.56). On Rule 56, the Court found that even its standards of materiality were too broad.

Somewhat unusually, however, the majority opinion stated that “but for” materiality and the rest of its test for inequitable conduct were subject to an exception – one for a patentee who “has engaged in affirmative acts of egregious conduct.” Slip op. at 29. Little else was said about the exception, leaving it largely unbounded in its structure and standards.

The opinion had a four judge dissent (written by Judge Bryson, joined by Judges Gajarsa, Dyk and Prost), but it dissented as to materiality alone. It would have retained the PTO standards of Rule 56.

In an interesting third opinion in this important *en banc* case, Judge O’Malley (recently arrived from being a district court judge), joined the majority as to intent, but dissented from the majority — and dissented from the dissent – as to materiality.

Judge O’Malley said both the majority and dissent “eschew[ed] flexibility in favor of rigidity.” Slip. op. concurrence at 4.

Of course, the opinion today may not be the final word, as the Supreme Court has not spoken to patent inequitable conduct since the 1940s.

Please click [here](#) to view the Federal Circuit decision.

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