

Federal Circuit Significantly Tightens Doctrine of Inequitable Conduct Today in It's En Banc Therasense Ruling

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The Federal Circuit today issued its awaited *en banc* opinion in *Therasense, Inc. v. Becton, Dickinson and Co.*, Appeal No. 2008-1511, defining the substantive standards for the inequitable conduct defense. As expected, the Court "tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." Slip op. at 24. For a detailed background of the *Therasense* case and description of the arguments, see our previous client alerts [here](#) and [here](#). Chief Judge Rader authored the majority opinion, joined by Judges Newman, Lourie, Linn, Moore, and Reyna. Judge O'Malley concurred in order to express her preference for a looser materiality standard. Judge Bryson dissented, joined by Judges Gajarsa, Dyk, and Prost.

After discussing the history of the doctrine and the problems engendered by routine assertions of the defense, the Court reaffirmed that inequitable conduct requires proof of materiality and specific intent to deceive, which are "separate requirements" and each of which must be proved by clear and convincing evidence.

The Court set forth the following more detailed standards for the intent prong:

- "[T]he 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." Slip op. at 24.
- "A district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa." *Id.* at 25.
- "[A] district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Id.*¹

¹ Judge O'Malley stated in her concurrence that she interpreted the majority opinion as not holding that it is impermissible for a court to consider the level of materiality as circumstantial evidence in its intent analysis. In her view, the majority opinion allows a district court to rely on the same items of evidence in both its materiality and intent inquiries, though the court must reach separate conclusions of intent and materiality and may not base a finding of specific intent to deceive on materiality alone, regardless of the level of materiality. (Op. at 3, n.1.) It remains to be seen how district courts deal with this comment

- “Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.... However, to meet the clear and convincing standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’” *Id.*
- “[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.* at 26.
- “Because the party alleging inequitable conduct bears the burden of proof, the ‘patentee need not offer any good faith explanation unless the accused infringer first ... prove[s] a threshold level of intent to deceive by clear and convincing evidence.’” *Id.*

The Court adopted a “but-for materiality” standard (with a limited exception discussed below) as was suggested might happen by our prior client alerts. The specifics of the Court’s holding with respect to the new materiality standard are set forth below:

- “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. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making the patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.” Slip op. at 27-28.
- “[E]ven if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO’s different evidentiary standards.” *Id.* at 28 (citing MPEP §§ 706 (preponderance of the evidence), 2111 (broadest reasonable construction)).
- The opinion is inconsistent in referring to materiality as being a bar to issuance of a “claim,” slip op. at 27-28, and elsewhere referring to materiality as meaning a bar to issuance of a “patent.” Slip op. at 28-29, 36. This may be an open issue that requires a further panel decision to resolve.

The Court maintained, however, a “limited exception” to the “but-for materiality” standard which applies to “cases of affirmative egregious misconduct.” Slip op. at 29. This exception expressly does **not** apply to nondisclosure of prior art references or failure to mention prior art references in an affidavit. The Court noted that exception was not limited to the filing of false affidavits, which was one example of affirmative egregious misconduct, but in fact could extend to any “affirmative acts of egregious misconduct.” Slip op. at 30. It remains to be seen whether this exception becomes cited in a manner to try to overcome the but-for standard.

The *Therasense* decision, particularly its redefinition of the materiality standard to an objective but-for standard, should have a significant impact and help curb the abuse of the defense as a last-resort allegation. Nonetheless, the decision does leave some areas of caution for patentees, including the continuing ability of the courts to infer intent from the totality of facts and an exception to the but-for standard for “egregious misconduct.” No doubt accused infringers will seek to broaden these gaps in future litigation. Patentees should remain vigilant when reviewing their portfolios and in their enforcement actions for opportunities for accused infringers to exploit the remaining avenues of attack.

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