

Making *Therasense* of the Inequitable Conduct Doctrine

June 1, 2011

In a split in its decision (6-1-4), the Federal Circuit's May 25, 2011 *en banc* opinion in *Therasense, Inc. v. Becton, Dickinson and Co.* attempts to unify the patch work of opinions on inequitable conduct, which is a judicially-created doctrine rooted in the U.S. Supreme Court's cases on the doctrine of "unclean hands" where egregious conduct had occurred.¹ (Full [decision](#)). The Federal Circuit emphasized that the previous assertions of the inequitable conduct doctrine based on its precedent have "plagued not only the courts but also the entire patent system."²

The majority opinion of the Federal Circuit in *Therasense* tries to balance the importance of patent applicants being honest in dealings with the United States Patent Office ("Patent Office") with the appropriate standard of review in determining whether inequitable conduct has actually occurred. As the Federal Circuit explained, the "low standards for intent and materiality" created by its previous opinions "have inadvertently led to 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[.]" Therefore, the Federal Circuit finally intervened[.] to tighten the standard and redirect the application of the inequitable conduct doctrine to benefit the public and the patent system by protecting against "egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence."³

The Decision

In *Therasense*, the Federal Circuit redefined the requirements for both the materiality and intent prongs, both of which are required to be proved by clear and convincing evidence, in making a determination of an inequitable conduct. The following charts illustrates the fractured nature of previous Federal Circuit opinions and how the *en banc* opinion unified the previous patch work of opinions:

Materiality

<u>Before</u>	<u>After</u>
<p>At least 5 different standards, including:</p> <ul style="list-style-type: none"> refutes or is inconsistent with a position the applicant takes in ... asserting an argument of patentability; a "reasonable examiner" would have considered the information or prior art "important" in deciding whether to allow the application; the misrepresentation was so material that the patent should not have issued; 	<p>But-For Test</p> <ul style="list-style-type: none"> the deception is only material if the USPTO would not have allowed the claim if it had been aware of the undisclosed information.

<ul style="list-style-type: none"> the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; and the misrepresentation may have influenced the patent examiner in the course of prosecution. 	
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Intent

<u>Before</u>	<u>After</u>
General intent to deceive based on totality of circumstances.	Specific intent to deceive with evidence of knowing and deliberate decision to deceive.

Although actual evidence is not required, the Federal Circuit found that "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.'"⁴ The Federal Circuit further explained "[i]n making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction."⁵

Finally, the Federal Circuit clarified that "a [district] court must weigh the evidence of intent to deceive independent of its analysis of materiality."⁶ Consequently, the Federal Circuit has abolished the sliding scale of intent and materiality.

Sliding Scale

<u>Before</u>	<u>After</u>
A strong showing of intent may be allow a weak showing of materiality, and vice versa.	No sliding scale.

Response by Patent Office

In its ruling, the Federal Circuit expressly rejected the definition of materiality in 37 C.F.R §1.56 ("Rule 56"). The Court stated that it was not bound by Rule 56, and that Rule 56 "sets such a low bar for materiality, adopting this standard would inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy."⁷

In reply to the Federal Circuit ruling, the Patent Office quickly issued a press release indicating that it is carefully studying the opinion and "expect to soon issue guidance to applicants regarding the materials they must submit to the Patent Office under

their duty of disclosure."⁸ It is unclear what actions the Patent Office may take, but if it amends Rule 56 to correspond with the *en banc* decision in *Therasense*, it could further strengthen the certainty of the standards required for equitable practice before the Patent Office.

What Does the Future Hold?

Going forward, the *Therasense* opinion may allow patent practitioners to reassess what documents they list in information disclosure statements and other filings with the Patent Office. Moreover, future Patent Office guidance should clarify the issue of what needs to be disclosed to the examiner. Additionally, it is anticipated that the *Therasense* opinion will reduce the number inequitable conduct allegations, but it may also require more flexibility from various patent rules of district courts, which routinely require allegations of inequitable conduct to be made before the close of discovery.

Notably, it did not take long for a U.S. district court to rely on this new ruling in deciding to deny a motion for a finding of unenforceability due to inequitable conduct. In *Ameranth, Inc. v. Menusoft Systems Corp., et al.*,⁹ the district court applied the new *Therasense* standard the day after it was issued, finding that although the "but-for" standard was met, the defendants failed to prove, by clear and convincing evidence, that there was specific intent to deceive the Patent Office.¹⁰

The Federal Circuit decision, however, did leave some potential new battlegrounds regarding the application of inequitable conduct. First, the Federal Circuit recognized the ability of district courts to infer intent from indirect evidence. Although the Court attempted to limit this loophole by stating "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found,"¹¹ it remains to be seen how district courts will apply this standard. Additionally, the Federal Circuit provided that when a "patentee has engaged in affirmative acts of egregious conduct" the misconduct is deemed to be material. This level of intent may overcome the requirement of "but-for" materiality having to be proved. The Federal Circuit suggests that this analysis should incorporate elements of the unclean hands doctrine, but it does not provide clear guidance on how this should be interpreted and suggests that this egregious conduct exception will allow for "flexibility to capture extraordinary circumstances."¹²

Although this is a way to curtail the allegations of inequitable conduct, it is not the end of the story, and it remains to be seen if the U.S. Supreme Court will weigh in on the application of inequitable conduct or attempt to harmonize the Federal Circuit's "but-for" test with the standards applied by other administrative agencies like the Securities Exchange Commission. We will continue to monitor the case and provide updates as it proceeds.

¹ *Therasense, Inc. v. Becton Dickinson & Co.*, 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, Slip Op. at 23.

² *Id.* at Slip Op. at 23.

³ *Id.* at Slip Op. at 18-19.

⁴ *Id.* at Slip Op at 25-26.

⁵ *Id.* at Slip Op at 28.

⁶ *Id.* at Slip Op at 25.

⁷ *Id.* at Slip Op at 34.

⁸ <http://www.uspto.gov/news/pr/2011/11-36.jsp>

⁹ *Ameranth, Inc. v. Menusoft Systems Corp., et al.*, No. 2:07-CV-271 (E.D.Tx May 26, 2011). At the conclusion of a five day jury trial in September 2010, which included testimony from the inventor, the jury returned a verdict that the asserted claims were

anticipated and obviousness. Subsequently, the defendants moved for a finding of unenforceable due to inequitable conduct post trial, and the District Court dismissed this motion based on *Therasense*.

¹⁰ *Id.* at 2.

¹¹ *Id.* at Slip Op at 25-26.

¹² *Therasense* at Slip Op at 30.