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## [Adjusting the Inequitable Conduct Doctrine: Federal Circuit Hears Oral Arguments \*En Banc\* in \*Therasense\*](#)

By [Gray M. Buccigross](#)

On November 9, 2010, the Federal Circuit, sitting en banc, heard oral arguments in *Therasense, Inc. v. Becton, Dickinson & Co.*, regarding the legal tests to be applied in determining whether a patent is unenforceable due to inequitable conduct. This has been a controversial issue over the last several years among practitioners, Federal Circuit judges, and industry groups, particularly Big Pharma. This article assumes some familiarity with the case and the issues. However, for background information on both, please [click here](#).

Plaintiff Abbott, Defendant Becton, Dickinson, Defendant Nova, and the PTO argued at the hearing. They addressed the following issues: (a) the standard for materiality; (b) intent; and (c) whether the facts of the case warranted a finding of inequitable conduct. The argument primarily focused on the materiality inquiry.

[Please note that while we have done our best to appropriately attribute comments to the specific Federal Circuit judges who made them, the associations may not be completely accurate. There is no official transcript available at this time.]

### **A. Materiality**

Under the PTO's current rules, information is "material" if it satisfies either Rule 56(b)(1) or 56(b)(2). Information is material under Rule 56(b)(1) if it "establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim." Information is material under Rule 56(b)(2) if it: "refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability."

Abbott argued that the standard for inequitable conduct case should be "but for" causation, where information is only material if the patent would not have otherwise issued, contending that:

(A) Supreme Court cases only found inequitable conduct where there had been "but for" causation.

(B) Rule 56(b)(2) would swallow Rule 56(b)(1).

(C) Equitable doctrines should not be used to punish; rather, the PTO can and should fill any void by policing misconduct.

(D) Anything less than "but for" causation will maintain the status quo, whereby applicants dump information while attempting to avoid characterizing or explaining that information.

The PTO argued that Rule 56(b) should be applied because:

(A) The "but for" standard allows too much mischief, while the "reasonable examiner" standard is too vague and causes "pathological overcompliance."

(B) Adjustment of the intent inquiry and *Exergen* (requiring specific pleading) will mitigate flooding.

(C) The PTO should have the first crack at information, so the market is not disrupted years later, and then an *ex post* analysis done via litigation.

Defendants argued that the PTO standard at the time of prosecution should be applied because:

- (A) Applicants should be judged by the standard to which the PTO held them.
- (B) Rule 56 is narrower than the reasonable examiner standard, and therefore not overly broad or vague.
- (C) Rule 56(b)(2) can be taken very literally. It is not about whether, for example, an invention is obvious at all, but whether it is obvious over the references relied on by the PTO. Further, disputes are not generally about Rule 56(b)(2).
- (D) The real problem is with overpleading, and not with excessive findings of inequitable conduct. *Exergen* and tightening the intent requirement should help with this.
- (E) The “but for” standard will permit misconduct, which the PTO cannot appropriately police.

The Court did not seem inclined to adopt a “but for” standard of causation. At least Judges Lourie, Dyk, and Moore expressed concern. Judge Lourie noted that the Supreme Court has struck down not just the patents that were procured by fraud, but additional patents as well. Judge Gajarsa raised some hypotheticals, seemingly pointing out that it would be hard to determine when a “but for” standard is met, and that it left much room for bad actors. Judges Linn and Dyk expressed concern that the “but for” standard would require an accused infringer to prove that prior art would have resulted in at least a rejection.

At least Judges Dyk, Newman, Moore, and Bryson also expressed concern about Rule 56(b)(2). The PTO acknowledged that applicants are currently “flooding” the PTO with references. Judge Dyk pointed out that Rule 56(b)(2) is “exactly what the law pretty much is right now.” Judge Dyk posed a hypothetical, asking what if there is a “tiny sliver of scientific opinion that is contrary to the position you are giving.” The PTO responded that this would need to be disclosed, but could be done in context. Judge Prost also repeatedly asked the parties how many people in the last ten years have been disciplined by the PTO for lack of candor. No one could answer.

Judge Newman noted that inequitable conduct is being pled in a large number of cases, but sustained in a small number of cases. This creates a “profound” litigation burden, and many small entities cannot afford to defend such charges. She did not see a reason that this would change if 56(b) remained an applicable standard. Judge Moore expressed that she was “having trouble seeing daylight between current Rule 56 and the reasonable examiner standard,” and later followed up that it’s “(b)(2) that seems to be the real problem.”

Judge Linn’s questioning indicated he was concerned with defendants’ proposal to track PTO standards, because the PTO can change its standards at any time, including back to the “reasonable examiner” standard.

## **B. Intent**

Aside from the facts of the case, the parties and the PTO seemed to agree that intent needed to be clarified. In particular, both the PTO and the Defendants argued that flooding of the PTO should be mitigated not by departing from Rule 56(b), but by: (1) following *Kingsdown* to require subjective intent and reject the standard requiring only that one “should have known” the materiality of the misrepresentation or undisclosed information; and (2) requiring that any inference of intent must be the single most reasonable inference.

## **C. Balancing of Materiality and Intent**

Judge Gajarsa took issue with the “tie-up of materiality with intent before we find intent.” Defendants argued that materiality can support a finding of intent, but only if there is other evidence as well (*e.g.*, motivation to deceive and knowledge). Defendants thus admitted that it is not proper to infer intent solely from materiality.

## **D. Specific Facts of the Case**

Overall, the arguments regarding the specific facts of the underlying case repeated the briefing and the arguments in the

underlying appeal and trial. Defendants contended that the facts fit squarely within the Rule 56(b)(2) “inconsistent” standard of materiality, that this was an egregious case, that there were adverse credibility findings, a finding of motivation to deceive, awareness, and an intentional decision not to disclose.

Abbott argued that if the Court finds the “should have known” standard is improper, then the decision must be reversed. Judge Moore noted the adverse credibility findings, however, and that Judge Alsup only recited the standard, rather than relied on it. Abbott responded that there was no evidence that Attorney Pope and Dr. Sanghera actually appreciated the materiality. Rather, Judge Alsup focused on the interpretation of the EPO briefs. Judge Dyk asked if the facts would satisfy the “but for” test. Abbott denied this, contending that the disclosures related to different substantive issues.

## **E. Implications for the Inequitable Conduct Doctrine**

Although we cannot predict how the Federal Circuit will come out on these issues, it seems obvious that the Federal Circuit will adjust the standard for materiality for purposes of determining whether a patent was procured through inequitable conduct. The Court seems very unlikely to adopt a “but for” standard of materiality. On the other hand, the parties seem to agree that the “reasonable examiner” standard is vague, overly broad, and therefore promotes overdisclosure. Further, the fact that numerous judges expressed concern regarding Rule 56(b)(2) suggests that the Federal Circuit may either tighten up the (b)(2) inquiry in inequitable conduct litigation or do away with it altogether.

The Federal Circuit also appears likely to clarify the intent standard. The Court will likely make clear that “should have known” is not good enough (per *Kingsdown*), and reinforce that the inference of intent must be the single most reasonable inference (per *Star Scientific* and *Scanner*). It remains to be seen whether, and if so to what extent, the Court will allow materiality to serve as a basis for inferring intent. Historically, judges have often inferred intent at least partly from materiality.

Notably, retired Federal Circuit Chief Judge Paul Michel projected at a November 12, 2010 Intellectual Property Owners Association webinar that there will be multiple opinions, both dissents and concurrences. He further predicted that there will be some modest adjustments to the materiality and intent inquiries. Additionally, he thought the Federal Circuit will take care not to push the initial burden of explaining any failure to disclose onto those associated with the patent prosecution.

*This article was originally posted on Sheppard Mullin's Life Sciences Law Blog, which can be found at [www.lifescienceslawblog.com](http://www.lifescienceslawblog.com).*

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