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**Keywords: inequitable conduct, doctrine of unclean hands, rule 56, equitable defenses**

**General: The Court changed the requirements for establishing an inequitable conduct defense by heightening the standards of both the intent and materiality elements. The heightened materiality standard requires “but-for” materiality. The heightened intent standard requires clear and convincing evidence of “specific intent.”**

*Therasense, Inc. v. Becton, Dickinson and Company*  
99 USPQ2d 1065  
(Decided May 25, 2011)

**I. Facts**

In the early 1980s, Medisense researchers developed a groundbreaking way of monitoring blood glucose levels in diabetic patients. The device comprised a sensor coated with enzymes that produced a small flow of electricity in the presence of glucose. This invention led to US Patent No. 4,545,382 (“the ‘382 patent”) and a counterpart European Patent No. 0078,636 (“the ‘636 patent”). A portion of the ‘382 patent discussed an *optional*, but *preferable*, protective membrane which acted as a barrier between the sensor and whole red blood cells, but allowed glucose to diffuse through.

The researchers also placed this sensor on a disposable test strip that could be placed into a digital meter to determine blood glucose levels. Medisense filed a patent application for the disposable test strip in 1984, and spent the next 13 years prosecuting it against multiple rejections for anticipation and obviousness over their own ‘382 patent. In 1996, Abbott acquired Medisense and appointed Lawrence Pope, one of Abbott’s in-house patent attorneys, to continue the prosecution of the disposable test strip. Pope worked with Medisense researcher, Dr. Gordon Sanghera, to present the claims of the disposable test strip application in a different light. Pope presented new claims to the PTO, and argued that the current art *did not* require a protective membrane against whole blood. To overcome the ‘382 patent, Pope interpreted the ‘382 patent to require a protective membrane for whole blood and provided an affidavit from Dr. Sanghera to support this interpretation.

However, a few years earlier, while prosecuting the ‘636 patent in the European Patent Office (EPO), European patent counsel distinguished over prior art by asserting that the ‘636 patent “does not have and must not have a semipermeable membrane.” In short, Pope made representations to the PTO in 1997 that the ‘382 patent *required* a membrane when European patent counsel made representations to the EPO in 1994 that the ‘636 patent *did not* require a membrane. However, in light of the affidavit and Pope’s new arguments, the Examiner granted US Patent No. 5,820,551 (“the ‘551 patent”) for the disposable test strip.

Shortly thereafter, Becton, Dickinson and Co. (“Becton”), which manufactures a blood glucose test strip of its own, sought a declaratory judgment of noninfringement of two US patents owned by Abbott. Abbott countersued, and alleged that Becton’s strips infringed not only those two patents, but also the recently acquired ‘551 patent. The Northern District of California determined after a bench trial that the ‘551 patent was *unenforceable for inequitable conduct* because Abbott did not disclose to the PTO the briefs submitted to the EPO. Furthermore, the district court awarded Becton millions of dollars in attorneys’ fees. Needless to say, Abbott appealed the inequitable conduct judgment; however, a panel of the Federal Circuit upheld the district court’s holding in a 2:1 decision. Three months later, the Federal Circuit granted Abbott with an *en banc* hearing, and suggested that the court was willing to reconsider almost everything about the inequitable conduct doctrine.

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## II. Issues

- A. Should this Court heighten the standards of both the intent and materiality elements of the inequitable conduct doctrine?
- B. Did the district court err in the standards it used to find the '551 patent unenforceable for inequitable conduct?

## III. Discussion

- A. Yes. The majority opinion, written by Chief Judge Rader, begins with an analysis of a trio of Supreme Court cases that used the doctrine of unclean hand to dismiss patent cases. The court characterizes these cases as all involving “particularly egregious misconduct,” such as perjury, the manufacture of false evidence, or the suppression of evidence. All these cases also involved “deliberately planned and carefully executed” schemes to defraud. The Court noted that these cases paved the way for the inequitable conduct doctrine that evolved to encompass a broader scope of misconduct, including the “mere nondisclosure of information to the PTO.” The remedy for an inequitable conduct finding also changed, from simply dismissing the lawsuit to unenforceability of the entire patent.

In addition to encompassing a broader scope of conduct, courts began to require a showing of both the inequitable conduct elements of materiality and intent with clear and convincing evidence. The Court recognized that the standards for establishing materiality and intent have fluctuated over time. For example, the Court cites to *Driscoll v. Cebalo* as establishing a low intent requirement by employing a “knew or should have known” standard. The courts further diluted the standards for both intent and materiality by placing them together on a “sliding scale.” The sliding scale allowed courts to find inequitable conduct even with a reduced showing of intent if the record indicated a stronger showing of materiality (and vice versa). Chief Judge Rader pointed out many negative effects of the inequitable conduct doctrine on the entire patent system:

“... low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality.”

Of particular relevance to patent prosecutors, Rader addressed the practice of “bury[ing] PTO examiners with a deluge of prior art references, most of which have marginal value.” In view of these unforeseen and unintended consequences, the Court directly stated that it will “tighten the standards for finding both intent and materiality” in an effort to redirect the doctrine of inequitable conduct. The Court issued clear standards for establishing the inequitable conduct defense:

1. Materiality standard: The materiality required to establish inequitable conduct is “but-for” materiality.
  2. Materiality standard exception: IF the patentee has engaged in affirmative acts of egregious misconduct, the misconduct is material.
  3. Intent standard: Clear and convincing evidence of specific intent is required.
  4. Intent must be separate from materiality, i.e. a “sliding scale” cannot be used.
- B. Yes. The district court held the '551 patent unenforceable for inequitable conduct because Abbott did not disclose briefs that it submitted to the EPO regarding the '636 patent (the European counterpart to the '382 patent). The Court indicated that the district

court found these briefs to be material under the Rule 56 materiality standard, but not under the new “but-for” materiality standard. Therefore, the Court vacated the district court’s findings of materiality, and remands the case to reconsider the issue of materiality in light of the new standard.

Furthermore, the district court found intent to deceive based on the fact that Abbott did not have a good faith explanation for their failure to disclose the EPO briefs. The Court indicated that the district court used a lower “should have known” standard in reaching its finding of intent, but not the clear and convincing evidence of specific intent standard. Therefore, the Court vacated the district court’s findings of intent, and remands the case to reconsider the issue of intent in light of the new standard.

#### **IV. Conclusion**

In an effort to address the unforeseen and unintended consequences that have arisen from the evolved form of the doctrine of inequitable conduct, the Federal Circuit has heightened the standards for finding both the intent and materiality elements.

#### **V. The Dissent**

Judge Bryson, in addressing the dissenting opinion, differed from the majority on one important issue: the heightened materiality standard. The dissenting opinion acknowledged that that negative impact of the inequitable conduct needs to be addressed. However, the dissent favors the broader standard of materiality – Rule 56:

- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
  - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
  - (2) 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.

The Dissent provides 2 arguments in support of its position. First, the Dissent argues that the PTO should determine what information is material and beneficial because it controls the prosecution process. Second, the Dissent asserts that the Majority’s heightened standard will not incentivize patent applicants to comply with the duty to disclose.

In response to these arguments, the Majority states that the PTO does not have substantive rule-making authority and that the ramifications of the inequitable conduct doctrine go well past its effect on the PTO (namely, into litigation).