



## The Federal Circuit Revisits and Revises the Inequitable Conduct Doctrine

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In an en banc opinion, *Therasense, Inc. v. Becton, Dickinson & Co.*, the Federal Circuit decried the effect of the inequitable conduct doctrine on the patent system and issued tightened evidentiary standards for satisfying that doctrine. As a result, courts will now demand more from an accused infringer to hold a patent unenforceable due to a patent applicant's behavior before the Patent Office. Six judges joined the majority, one judge concurred in part and dissented in part, and four judges dissented.

### The development of inequitable conduct

Writing for the majority, Judge Rader started with a historical overview of the origin and evolution of the court's inequitable conduct jurisprudence, dating back to the trio of Supreme Court cases that gave rise to the doctrine—*Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). Over time, broader notions of misconduct evolved as well as a broader and more potent remedy—unenforceability of the patent rather than dismissal of the case. At the same time, the evidentiary showing necessary to establish inequitable conduct fluctuated and ultimately lowered.

The Federal Circuit concluded that the decreased evidentiary threshold for establishing inequitable conduct harmed the patent system by increasing the cost and complexity of cases, reducing the likelihood of settlement, burdening courts, straining PTO resources, increasing PTO backlog, and diminishing patent quality. As a result, the court in *Therasense* decided to "tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."

### The standard for inequitable conduct

The essential elements of inequitable conduct remain unchanged:

To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable.

Instead, the Federal Circuit revised the evidentiary standards that an alleged infringer must meet to satisfy the "intent" and "materiality" elements of the doctrine.

### An accused infringer must show that the applicant had actual intent to deceive the PTO

"To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO" by showing through clear and convincing evidence that a



patent applicant: 1) knew of a reference; 2) knew that the reference was material; and 3) made a deliberate decision to withhold the reference.

Although courts may continue to infer intent from indirect and circumstantial evidence, “the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.” Put otherwise, if there are multiple reasonable inferences, there can be no finding of intent.

Under this heightened standard, it is no longer enough for an accused infringer to show that an applicant “should have known” a reference or omission was material. In addition, district courts no longer may use a “sliding scale” to find intent based on a strong showing of materiality, nor infer intent from materiality alone. “Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality.” The patentee is under no obligation to come forward with a good faith explanation for the alleged omission or misrepresentation until the accused infringer satisfies its burden. Consequently, the absence of such an explanation cannot alone prove intent.

### **An accused infringer must now show but-for materiality**

“[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality. 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.” If a patent would have issued despite an applicant’s misconduct, the applicant received no benefit for that misconduct and thus there can be no finding of inequitable conduct. The Federal Circuit declined to adopt the PTO’s “reasonable examiner” standard of materiality embodied in Rule 56 of the MPEP as the standard for establishing inequitable conduct because Rule 56 sets a “low bar for materiality” and “resulted in the very problems” that the majority sought to address.

The court did carve out one exception to but-for materiality that is rooted in the Supreme Court’s unclean hands cases: “When the patentee has engaged in affirmative acts of egregious misconduct ... the misconduct is material.” The court noted that this exception, which punishes “affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision, ... strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.”

### **Five judges dissent from the majority’s imposition of but-for materiality**

All the judges appeared to agree that the inequitable conduct doctrine needed adjustment. However, while all agreed with the heightened intent standard, the court was nearly equally divided as to the threshold required to satisfy materiality.

Judge O’Malley concurred in part, but dissented from the majority’s rigid understanding of materiality, suggesting that materiality could be found where (i) but for the conduct the patent would not have issued; (ii) the conduct constitutes a false or misleading misrepresentation; or (iii) the conduct is so offensive that the application process was wholly undermined. Judge Bryson, writing for the four dissenters, argued that courts should adhere to the PTO’s “reasonable examiner” notion of materiality delineated in Rule 56 of the MPEP. The dissent also disputed the majority’s interpretation of Supreme Court precedent and noted that its approach was a “significant and ... unwise departure” from Federal Circuit jurisprudence.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors:

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