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Federal Circuit Tightens Inequitable Conduct Standards: What Does This Mean for Patent Practice in the Future?

On May 25, 2011, the en banc Federal Circuit raised the bar for establishing inequitable conduct in patent infringement cases. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1511 (Fed. Cir. May 25, 2011). We summarize the decision and then suggest how it may impact patent practice going forward.

Summary of the *Therasense* decision

The Federal Circuit in *Therasense* has adopted more stringent standards for proving inequitable conduct in an effort to reduce overuse of the doctrine in patent litigation. Chief Judge Rader, writing for a six-judge majority, tightened the standards for finding both materiality and intent to deceive. Accused infringers now must show by clear and convincing evidence both that: (1) but-for the failure to disclose, the PTO would not have allowed a claim to issue, and (2) the patentee made a deliberate decision to withhold a known material reference.

The most significant change is to the materiality standard. The Federal Circuit has rejected the “reasonable examiner” standard, instead holding “as a general matter,” that “the materiality required to establish inequitable conduct is but-for materiality.” *Id.* at 27. This means that information is material only “if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Id.* In making this but-for determination, courts “should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.” *Id.* at 28.

The Court left open an exception to its general rule requiring but-for proof of materiality in cases of affirmative egregious misconduct. “When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material” even without a showing of but-for materiality. *Id.* at 29.

The changes to the intent standard are less drastic but resolve a prior split of authority on the showing required to prove intent. The Court clarified that a finding of intent to deceive is appropriate only where clear and convincing evidence shows “that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Id.* at 24. The Court rejected the “sliding scale” approach where weaker evidence of intent may be sufficient in view of a stronger showing of materiality. *Id.* at 25. Instead, courts must weigh evidence of intent independent of materiality. *Id.*

The Court recognized that “smoking gun” evidence of intent is rare and affirmed that courts “may infer intent from circumstantial evidence.” *Id.* But to meet the clear and convincing standard, an inference of intent to deceive “must be ‘the single most reasonable inference able to be drawn from the evidence’” and “must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.” *Id.* at 25-26 (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) and *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988) (en banc)).

Four judges joined a dissenting opinion authored by Judge Bryson. The dissent maintained that the adoption of a but-for standard for materiality is a significant and unwise departure from precedent that

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would not provide sufficient incentives for applicants to comply with their disclosure obligations. The dissent instead would have adhered to the materiality standard set forth in the PTO's disclosure rule, Rule 56.

Judge O'Malley, the only sitting Federal Circuit judge to have previously served as a district court judge, filed a separate opinion concurring in part and dissenting in part. She agreed with the decision to vacate and remand, but rejected the "hard and fast rules" of the majority and dissent. Instead, recognizing the equitable nature of the doctrine, she would have provided flexibility to district courts to exercise their discretion in inequitable conduct inquiries.

Should the litigants opt to petition for certiorari, the fractured 6-1-4 en banc panel shows division in the Federal Circuit that could prompt Supreme Court review.

Impact on Patent Practice Going Forward

We now consider how *Therasense* will impact patent litigation and prosecution going forward.

In the patent litigation context, we expect a short-term increase in the number of motions to dismiss inequitable conduct claims and motions for summary judgment of no unenforceability. In the longer term, we expect to see fewer inequitable conduct claims. Inequitable conduct claims are less likely to be successful given the higher bar for showing materiality and intent. Furthermore, litigants may find it more difficult, if not impossible, to plead inequitable conduct. The Federal Circuit recently heightened the pleading standard for inequitable conduct.¹ *Therasense* further heightens the pleading burden by raising the underlying standards for inequitable conduct. In most cases, it will be difficult to plead inequitable conduct without first conducting discovery. However, it may be difficult to obtain discovery without first pleading unenforceability. We expect this to be a recurring Catch-22 in patent litigation that may prevent assertion of inequitable conduct in some cases. With fewer inequitable conduct claims, patentees can expect lower costs and reduced risks of patent unenforceability in the future.

The decision's impact on patent prosecution likely will be less profound. The Court did not diminish the importance of satisfying the duty of disclosure, and well-advised patent applicants will continue to do so diligently. In view of the "but-for" test, however, patent prosecutors probably will be less inclined to submit at least two types of references: (1) those that published after an application's filing or earliest priority date, and (2) those that are marginally related to an application's claimed subject matter. Nevertheless, these types of references likely will continue to be disclosed by many risk-averse attorneys and applicants.

We also expect that many attorneys will continue to disclose certain documents from the file histories of related U.S. cases and foreign counterpart applications, including office actions, references cited therein, and responses to the office actions. The Court failed to address the necessity of this practice, and the *McKesson* decision in general. *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007). These lingering uncertainties, we hope, will be addressed in the near future by the courts and the PTO.

¹ The Federal Circuit requires "identification of the specific who, what, when, where, and how of the material misrepresentation or omission" and "sufficient allegations of underlying facts from which a court may reasonably infer [intent to deceive]." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 525 F.3d 1312, 1327 (Fed. Cir. 2009).

For these reasons, we believe the Court's decision will minimally impact the disclosure practice of most patent prosecutors, especially in the short term. Habits may change, however, as the PTO generates commensurate new guidelines and the lower courts clarify the materiality and intent standards. Until then, patent attorneys and applicants should continue their diligent efforts to satisfy the duty of disclosure, while taking comfort in knowing that issued patents will be less susceptible to a charge of inequitable conduct.



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