



Therasense v. Becton: En Banc Federal Circuit Reworks Inequitable Conduct

On May 25, 2011, a fractured Federal Circuit issued the en banc *Therasense v. Becton*¹ decision addressing the proper standard for inequitable conduct. Every single written decision appeared to agree that there was a problem with the judicially created inequitable conduct doctrine, although the three opinions differed on the proper standard for materiality. The majority opinion, authored by Judge Rader and joined by five other judges, overruled the Federal Circuit's recent inequitable conduct jurisprudence and adopted a high materiality standard that only applies in the case of egregious behavior or where but-for the conduct the patent would not have issued. Judge O'Malley, concurring in part and dissenting in part from the majority decision, asserted that the equitable doctrine required a more flexible approach than proposed by either the majority or the dissent. The dissent, authored by Judge Bryson and joined by three other judges, continued to advance the lower materiality standard set forth by PTO Rule 56.

I. Facts

Abbott filed the application that led to the '551 patent in suit in 1984. During prosecution, Abbott made certain arguments that were potentially inconsistent with arguments it had previously made during prosecution of a European counterpart. In 2004, Becton sued Abbot for declaratory judgment of noninfringement of certain patents, and Abbott countersued for infringement of the '551 patent. Following a bench trial, the district court found that the '551 patent was unenforceable for inequitable conduct because Abbott did not disclose the briefs it filed with the European Patent Office to the PTO. On appeal, the Federal Circuit affirmed the inequitable conduct decision, although Judge Linn dissented. The Federal Circuit then granted Abbott's petition for rehearing en banc.

II. The Majority Opinion Created New Intent And Materiality Standards.

In the en banc majority opinion, Judge Rader first reviewed a trio of Supreme Court cases from 1933 to 1945 that applied unclean hands to dismiss patent cases—*Keystone*, *Hazel-Atlas*, and *Precision*. The court explained that these unclean hands cases formed the basis for the doctrine of inequitable conduct, which had developed and evolved over time. The court noted that *Keystone* and *Hazel-Atlas* involved the manufacture and suppression of evidence and *Precision* involved suppression of evidence and perjury. The court explained that all three cases involved particularly egregious misconduct, although they did not present any specific standard for materiality.

The court next pontificated on the problems that have arisen from the doctrine of inequitable conduct over the years—including applicants' over-disclosing art to the PTO for fear of inequitable conduct claims to litigants' over-asserting the doctrine, increasing cost and complexity of cases. After cataloging these problems, the court



concluded, “[t]his court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”

A. No Sliding Scale: Intent And Materiality Must Both Be Met.

The court held that intent and materiality are separate requirements that must both be met before a finding of inequitable conduct. The court warned that “[a] district court should not use a ‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.” The court further explained that intent cannot be inferred solely based on materiality.

B. Intent Standard: “Should Have Known” Does Not Satisfy The Intent Requirement.

The court also considered the standard of intent required for an inequitable conduct finding. The court recited the accepted law that “[t]o prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.” It then concluded that “should have known” did not satisfy that intent requirement. Specifically, the court explained that “the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” The court reasoned that this intent standard was consistent with the Supreme Court cases that first developed the rule.

The court recognized that direct evidence of deceptive intent is unusual, and concluded that a district court could infer intent from indirect and circumstantial evidence. It reiterated that when there are multiple inferences that can be drawn, deceptive intent cannot be found. The court also repeated that a patentee need not come forward with any explanation unless the accused infringer first proved the threshold level of intent by clear and convincing evidence.

C. Materiality Standard: But-For Standard Or Affirmative Acts Of Egregious Misconduct.

Relying on the 1928 *Corona* Supreme Court case, the court concluded that when a patentee makes a misrepresentation to the PTO that does not affect the issuance of the patent, such information is not material. Thus, the court rejected the court’s previous materiality standard and adopted a much stricter but-for standard. Specifically, the court concluded “[w]hen 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.” The court reasoned that a patentee obtains no advantage from misconduct if the patent would have issued anyway.



The majority rejected the dissent's criticisms that this standard would only apply to patents that would be invalid as anticipated or obvious because of the same prior art rendering the patent unenforceable. The court explained that because of the higher standard for invalidating an issued patent, a prior art reference could on one hand be material because it would have blocked patent issuance and at the same time not rise to the level required for invalidation of an issued patent.

The court recognized an exception to the but-for materiality requirement, however. The court explained that in the case of "affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material." The court reasoned that "a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent." But the court explained that "neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality."

The majority rejected the dissent's criticism of the exception, explaining that the new materiality standard "includes an exception for affirmative acts of egregious misconduct, not just the filing of false affidavits." The court further defended the new standard by asserting that it was consistent with the early unclean hands cases that all dealt with egregious misconduct.

The court rejected the prior lower materiality standard set forth in PTO Rule 56—and advanced by the dissent—explaining that it was not bound by PTO. The court further noted that there was strong public interest in reigning in inequitable conduct and that its standard had been advanced by several amicus organizations.

Based on the new standard, the Federal Circuit remanded the case back to the district court for a further determination on inequitable conduct.

II. Judge O'Malley's Concurrence in Part and Dissent in Part: The Equitable Doctrine Of Inequitable Conduct Requires A Flexible Approach.

Judge O'Malley recognized that equitable principles and remedies are imprecise by design. She also praised the majority's attempt to address attorneys' requests for precision and clarity in the inequitable conduct doctrine. But she dissented from the test outlined in the majority's decision, explaining that it failed to "acknowledge and remain true to the equitable nature of the doctrine it seeks to cabin." She asserted that "both the majority and dissent strain too hard to impose hard and fast rules."



Judge O'Malley cited several Supreme Court cases that explained that equitable doctrines must be applied flexibly, and argued that both the majority's adopted test and the dissent's proposed test were too rigid. She reasoned that "[p]olicy concerns cannot, however, justify adopting broad legal standards that diverge from doctrines explicated by the Supreme Court. A desire to provide immutable guidance to lower courts and parties similarly is not sufficient to justify the court's attempt to corral an equitable doctrine with neat tests."

Addressing one of the majority's reasons for limiting the inequitable conduct doctrine, Judge O'Malley suggested she would overrule the cases that cause inequitable conduct to render all claims of the patent and, in some cases, related patents unenforceable. She asserted that this remedy is not compelled by statute and is not consistent with the equitable doctrine. Instead, she suggested, a district court should be free to exercise its discretion to render fewer than all claims unenforceable or fashion some other reasonable remedy, as long as the remedy is "commensurate with the violation."

Judge O'Malley also suggested that if the equitable doctrine of unclean hands remained viable in cases of misconduct before the PTO, allegations of unclean hands could replace the inequitable conduct claims that the majority sought to curb.

Considering her proposed flexible test, Judge O'Malley asserted that she would affirm the district court's inequitable conduct determination.

III. Judge Bryson's Dissent: Lower Materiality Standard In PTO Rule 56 Should Still Apply.

The dissent recognized that there is consensus that the law of inequitable conduct needs adjustment. The dissent also agreed with the majority's determinations of intent and sliding scale. But the dissent strongly disagreed with the materiality standard set forth by the majority, asserting the PTO's Rule 56 should apply, as the PTO is in the best position to know what information the examiners would consider material. The court also reasoned that the majority's higher standard did not provide the proper incentives for patent applicants to comply with the disclosure obligations of the PTO.

The dissent asserted that the materiality standard adopted by the majority was inconsistent with Federal Circuit case law. It explained that the court had repeatedly rejected a "but for" test as too narrow. Further, the dissent explained, the majority's decision did not just reform the doctrine of inequitable conduct "but comes close to abolishing it altogether." The majority explained that "[i]f a failure to disclose constitutes inequitable conduct only when a proper disclosure would result in rejection of a claim, there will be little incentive for applicants to be candid with the PTO, because in most instances the sanction of inequitable conduct will apply only if the claims



that issue are invalid anyway.” The court explained “there is little to lose by following a course of deceit.”

The dissent also reviewed the Supreme Court cases the majority relied upon in support of its decision, and asserted that those cases did not turn on whether the fraudulent conduct was the “but for” cause of the issuance of the patent. The court criticized the majority’s reliance on the *Corona* case, asserting that case predated the creation of the inequitable conduct doctrine and had never been cited by the Supreme Court in any case addressing unclean hands or inequitable conduct. The court also argued that the *Corona* court’s assertion that the affidavits were not the basis for the issuance of the patent did not restrict inequitable conduct to a but-for test.

The dissent defended its own proposed Rule 56 test noting, among other things, that while inequitable conduct is an equitable defense, the purpose of the court-made doctrine is the same as the purpose of Rule 56. The dissent also noted that the PTO supported its proposed test.

Considering its proposed test, the dissent asserted that it would affirm the district court’s inequitable conduct determination.

IV. Conclusion

While the majority set forth a high standard of materiality—one that the dissent asserted comes close to abolishing inequitable conduct altogether—it remains to be seen how that high standard will be applied. The majority asserts that its but-for test would apply if the PTO “would not have allowed a claim had it been aware of the undisclosed prior art.” Presumably, this means that if the claim would have required narrowing or amending, any nondisclosure would be material, although it remains to be seen how courts will apply the doctrine. Also, the majority did not strictly limit the materiality standard to but-for. Instead, the court explained that affirmative acts of egregious misconduct can be material. It, again, remains to be seen how this exception to the but-for standard will be applied.

¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595 (Fed. Cir. May 25, 2011).