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## Inequitable Conduct as a Defense to Patent Infringement in the Wake of *Therasense*: Defining “Materiality” and “Specific Intent”

On May 25, 2011, the U.S. Court of Appeals for the Federal Circuit issued a landmark decision changing the standards for proving inequitable conduct as a defense to patent infringement. In *Therasense, Inc. v. Becton, Dickinson & Co.*, the court held that to establish inequitable conduct an accused infringer must prove, first, that the patentee acted with specific intent to deceive or made a deliberate decision to withhold information from the United States Patent and Trademark Office (“PTO”); and, second, that “but for” the patentee’s misrepresentations or omissions, the PTO would not have issued the patent.

*Therasense* addressed a patent for disposable blood glucose test strips developed for the treatment of diabetes. The patentee sought to claim glucose strips that lacked a membrane on the electrode used for testing, over prior art stating that a membrane was “optionally, but preferably” included on the test strip. Because the patentee also owned the prior art, the Examiner required a declaration that the prior art had required a membrane. The patentee’s R&D director averred that a person of ordinary skill would understand the prior art’s use of “optionally, but preferably” language as requiring a membrane, and the Examiner allowed the claims. During the earlier prosecution of the European counterpart to the same prior art, the patentee had, however, submitted a declaration, from the same expert, stating that the prior art *did not* require a membrane. When the patentee asserted the patent against Becton, Dickinson & Co., the alleged infringer argued that it was unenforceable due to the patentee’s inequitable conduct by failing to disclose properly the prior art to the PTO.

### History of Inequitable Conduct

Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. The doctrine originated with Supreme Court cases that applied the common-law doctrine of unclean hands to dismiss patent infringement cases involving egregious misconduct by the patentee, including the suppression of evidence, perjury and the submission of false evidence to the PTO. Inequitable conduct gradually evolved to encompass misconduct broader than unclean hands, including the simple failure to disclose of information to the PTO. Inequitable conduct also acquired a powerful remedy: unenforceability of the entire patent rather than mere dismissal of the instant suit.

### The Increase of Inequitable Conduct Claims

Federal courts have long required inequitable conduct claimants to show that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. Over time, the showing needed to establish the “materiality” and “specific intent” prongs of inequitable conduct weakened as courts promoted full disclosure to the PTO. Before *Therasense*, courts evaluated intent and materiality together on a “sliding scale,” that allowed a finding that a patent was unenforceable if the record contained a strong showing of materiality and a reduced showing of intent, or vice versa.

Whether caused by or coincidental to the evolution of the standard governing claims of inequitable conduct, the frequency of inequitable conduct defenses alleged in patent infringement cases has increased, leading to an expansion of discovery into pre-filing corporate practices, disqualification of prosecuting attorneys from the patentee’s litigation team, and, presumably, a lower probability of settlement. Inequitable conduct allegations “increase[d] the complexity, duration and cost of patent infringement litigation that [was] already notorious for its complexity and high cost” and frequently triggered antitrust and unfair competition claims, as well as additional litigation over the crime-fraud exception to attorney-client privilege.

The *Therasense* court concluded that then-current standards for proving inequitable conduct placed an undue strain not only on the judiciary, but also on the patent system as a whole. According to the court, patent applicants frequently disclosed too much prior art for the PTO to consider meaningfully, and failed to explain the significance of the prior art they disclosed, all out of fear that to do otherwise would risk an inequitable conduct claim. That risk was substantial because the remedy for inequitable conduct is the “atomic bomb of patent law.” Unlike validity defenses, which are specific to a particular claim, a finding of inequitable conduct regarding single claim renders the entire patent unenforceable and the problem cannot be solved by reissue.

### *Therasense* Set New Standards for “Materiality” and “Intent”

To “redirect a doctrine that has been overused to the detriment of the public,” the *Therasense* court decided to “tighten the standards for finding both [the] intent and [the] materiality” required to prove inequitable conduct. *Therasense* eliminated the sliding scale, holding that “intent and materiality are separate requirements” that must be evaluated independently.

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Under *Therasense*, the accused infringer must show intent by proving that the patentee acted with the specific intent to deceive the PTO. In cases involving nondisclosure of information, the accused infringer must show by clear and convincing evidence that the applicant made a deliberate decision to withhold known material prior art; it is insufficient that the applicant “should have known” of the materiality of the undisclosed prior art. The *Therasense* court conceded that, because direct evidence of deceptive intent is rare, “the district court may infer intent from indirect and circumstantial evidence” so long as the specific intent to deceive is “the most reasonable inference able to be drawn from the evidence.” In cases where multiple reasonable inferences can be drawn, a court cannot find intent to deceive. The party alleging inequitable conduct bears the burden to prove by clear and convincing evidence a threshold level of intent to deceive before the patentee need offer good faith explanation.

The Federal Circuit had previously attempted to reduce inequitable conduct claims by modifying only the intent prong of the analysis. See, e.g., *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). In *Therasense*, the court also adjusted the standard for materiality.

*Therasense* held that, to establish a claim of inequitable conduct, the accused infringer must show “but-for materiality.” When an applicant fails to disclose prior art, the prior art is “but-for” material if the PTO would not have approved the patent had it known of it. To determine patentability in this context, the court “should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.”

The “but-for” test may be similar to a determination of invalidity. If a claim is invalidated based on a deliberately withheld reference, that reference would necessarily be material because invalidity “requires clear and convincing evidence,” a higher evidentiary burden than used in prosecution at the PTO. Even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may nevertheless qualify as material if it would have blocked the patent’s issuance under the PTO’s evidentiary standard.

*Therasense* adopted “but-for” materiality to ensure that inequitable conduct would be applied only when the “patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” If the patent would have issued anyway, the patentee did not obtain an unfair advantage from the misconduct, and enforcement would not injure the public.

In adopting its new standard for materiality, *Therasense* expressly declined to use the PTO’s Rule 56 definition, which covers *any information* that “refutes or is inconsistent with” any position the applicant took regarding patentability. The court rejected that definition because “even if information would be rendered irrelevant in light of subsequent argument or explanation by the patentee, it could still be considered material.” Because Rule 56 encompasses anything “marginally relevant” to patentability, its low standard of materiality would “inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy.”

## The Exception to “But-For” Materiality: Affirmative Egregious Acts

Although the but-for rule must generally be satisfied to satisfy the materiality prong of inequitable conduct under *Therasense*, the court recognized an exception for affirmative acts of “egregious misconduct.” In cases such as the filing of an unmistakably false affidavit, the misconduct is deemed material. The court’s exception incorporates elements of the early unclean hands cases decided by the Supreme Court. These cases addressed “deliberately planned and carefully executed schemes to defraud the PTO and the courts,” observing 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.” Because the exception does not apply to mere nondisclosure of prior art references or the failure to disclose such references in an affidavit, claims of inequitable conduct based on such omissions still require proof of but-for materiality. By creating an exception to punish affirmative egregious acts without penalizing immaterial omissions, *Therasense* seeks to strike a balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct that the *Therasense* majority believed have “plagued” courts and the U.S. patent system as a whole.

## Practical Implications of *Therasense*

The *Therasense* court was closely divided, and what constitutes inequitable conduct may ultimately be decided by the Supreme Court. In the meantime, the heightened standard required to show “materiality” makes it more difficult for accused

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infringers to establish inequitable conduct as a defense to patent infringement. The *Therasense* dissent argued that the heightened standard is too restrictive, and makes inequitable conduct a redundancy because only invalid claims could be held unenforceable:

Under this court's new rule, an applicant who conceals information with the intent to deceive the PTO will be free to enforce his patent unless it can be proved by clear and convincing evidence that the new patent would not have issued but for the fraud. Even though the majority justifies its new rule in part by asserting that it will improve the prosecution of patents before the PTO, I am convinced that the new rule is likely to have an adverse impact on the PTO and the public at large, a view that – significantly – is shared by the PTO itself.

It remains to be seen whether or not the heightened materiality standards announced by the *Therasense* majority will result in the adverse consequences predicted by the dissent. Even if the new materiality standard reduces the incentives to make a full initial disclosure to the PTO, the test will likely ease the burden on the patent system and courts created by “overdisclosure” to the PTO and the proliferation of inequitable conduct claims. In turn, the use of the new *Therasense* standard may allow the courts and the PTO to focus on the most egregious and potentially damaging cases of patent infringement, that were the most deserving of scrutiny in the first place.