

Therasense v. Becton Dickinson:
Inequitable Conduct Defense Eviscerated

On May 25, 2011, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") issued a long anticipated opinion in *Therasense, Inc. v. Becton, Dickinson and Co.* Sitting *en banc*, the Federal Circuit, with Chief Judge Randall Rader writing for the 6-1-4 majority, set forth a new framework for considering inequitable conduct claims, one that stresses separate determinations as to intent and materiality, and substitutes a "but-for" materiality standard for the existing materiality standard as embodied in the PTO's Rule 56. Applying the new standard to the facts of the case, the court concluded that inequitable conduct had not been proven, and remanded the case to the district court for further proceedings consistent with the Federal Circuit's opinion.

Setting the stage for its unveiling of the new analytical framework, the Federal Circuit (hereinafter simply "the court") reiterated that "[t]o 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]." Noting that existing inequitable conduct doctrine had become "a significant litigation strategy," in part because its remedy of patent unenforceability was "the 'atomic bomb' of patent law," and had spawned many evils, chief among them expanding discovery, discouraging litigation settlement, increasing the complexity, duration and cost of patent infringement litigation and prompting fearful patent applicants and prosecutors to bury patent examiners in "a deluge of prior art references, most of which have marginal value," the court admitted that, in the past, it had "tried to address the proliferation of inequitable conduct charges by raising the intent standard alone," but, clearly frustrated, the court conceded this "did not reduce the number of inequitable conduct cases before the courts and did not cure the problem of over disclosure of marginally relevant prior art to the PTO."

"To address these concerns, this court adjusts as well the standard for materiality.

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"This court holds that, as 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. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of evidence standard and give claims their broadest reasonable interpretation."

The court reasoned, relying on early Supreme Court decisions that heralded the doctrine, that "[a]s an equitable conduct doctrine, inequitable conduct hinges on basic fairness," and "[b]ecause inequitable conduct renders an entire patent (or even a patent family) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim."

The court immediately recognized "an exception in cases of affirmative egregious misconduct." "When patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably



false affidavit, the misconduct is material." However, "[b]ecause 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. By creating an exception to punish affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision, this court strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct."

The court also tightened the standards for finding intent. After referring to language from an earlier precedent that "[i]n a case involving a nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference," the court clarified "[i]n other words, the accused infringer must prove by clear and convincing evidence that the applicant [(1)] knew of the reference, [(2)] knew that it was material, and [(3)] made a deliberate decision to withhold it."

The court emphasized that "[i]ntent and materiality are separate requirements," and both must be found in order for an inequitable conduct defense to lie. The court renounced the practice of using "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 indicated that "a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive."

The court acknowledged that "[b]ecause direct evidence of intent is rare, a district court may infer intent from indirect and circumstantial evidence." However, the court cautioned that in order "to meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" The court explained, "the evidence 'must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.' * * * Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found."

The court provided the further guidance that "[b]ecause the party alleging inequitable conduct bears the burden of proof, the 'patentee need not offer any good faith explanation [for the failure to disclose] unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.' * * * The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive."

And, if that weren't already enough to lift the spirits of patentees and prosecutors, the court categorically rejected the definition of "materiality" in the PTO's Rule 56, commenting that "reliance on this standard has resulted in the very problems this court sought to address by taking this case en banc." According to that rule, which, presumably, the PTO must now revise, a reference is material if (1) it establishes a *prima facie* case of the unpatentability of any claim either by itself or in combination with other information; or (2) it refutes or is inconsistent with a position the applicant has taken either opposing a PTO argument of unpatentability or in supporting applicant's own argument of patentability. According to the court, the first prong was "overly broad" in that it included information would be "considered material even if the information would be rendered irrelevant in light of subsequent argument or explanation by the patentee." Likewise, the second prong was also too broad in that it "broadly encompasses anything that could be considered marginally relevant to patentability."

The single concurrence (Judge O'Malley) accepts "but-for" materiality in most cases, but additionally would permit the district court judge to fashion an appropriate remedy in cases where patentee's conduct did not



meet the "but-for" materiality standard yet was "so offensive" as to justify some sanction. The four dissenters (Judges Bryson, Gajarsa, Dyk and Prost) would retain the current Rule 56 standard of materiality, deferring to the PTO as being in the best position to judge its own needs.

It is difficult to conceive, and remains to be seen how the PTO can adjust the duty of disclosure to be commensurate with after-the-fact "but-for" materiality. Certainly, anticipatory prior art, whether publications or prior uses or sales, would always be "but-for" material. Beyond this, however, things get murky. Thus, for example, there should logically be no duty to disclose a reference that by itself established a *prima facie* case of obviousness where the applicant had disclosed in the application specification or held in hand evidence rebutting such *prima facie* case. Yet, one can easily imagine that the PTO may still want applicants to disclose these types of references. Ultimately, the PTO may be forced to require a higher duty that seemingly could be ignored by applicants in view of *Therasense*, but not by practitioners who would remain subject at least to PTO discipline for non-compliance. Such a dichotomy could implicate the attorney-client privilege. The challenges facing the PTO are great.

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