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Federal Circuit Raises the Bar for Proving Inequitable Conduct

Therasense, Inc. v. Becton, Dickenson and Co., 2008-1551 (Fed. Cir. May 25, 2011) (en banc).

Over the 13 year prosecution history of the '551 patent-in-suit, the U.S. Patent and Trademark Office ("USPTO") rejected the original application multiple times for anticipation and obviousness over the prior art '382 patent also owned by the patentee. After studying the rejections, counsel for the patentee adopted a new approach and argued that the '551 patent was neither obvious nor anticipated because based on specific language in the '382 patent specification, i.e., the '382 patent *required* a particular component. Counsel presented this argument, and the patentee submitted a declaration of its director of research and development to support this argument. Previously, the patentee's European lawyers were prosecuting the European counterpart to the '382 patent, and they argued that the identical language in the specification of the European counterpart to the '382 patent made the component merely *optional*.

The district court held that the '551 patent was unenforceable for inequitable conduct because the applicant did not disclose to the USPTO its briefs to the EPO regarding the interpretation of the prior art '382 patent. The Federal Circuit panel affirmed the finding of unenforceability with a dissent by Judge Linn. Upon rehearing the appeal *en banc*, the Federal Circuit vacated the inequitable conduct judgment and remanded.

The majority opinion written by Chief Judge Randall Rader began with a history of the judicial doctrine of inequitable conduct and traced the roots of the doctrine to three Supreme Court decisions addressing unclean hands. Although developing out of these unclean hands decisions, inequitable conduct developed several significant differences from unclean hands. In particular, inequitable conduct could be found from non-disclosure of information to the PTO, included a remedy of unenforceability for the entire patent, and had a different test—materiality and intent.

Because of these significant differences from unclean hands, inequitable conduct came to be a standard litigation tactic. Indeed, some statistics indicate that inequitable conduct is alleged as a defense in 80% of patent infringement cases. According to the majority, "inequitable conduct has plagued not only the courts but also the entire patent system." *Op.* at 23. In particular, the court explained how patent prosecutors are now "burying" patent examiners with prior art references to avoid allegations of inequitable conduct. In summary, the "low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality." *Id.* at 24. Responding to these perceived problems with the judicial doctrine of inequitable conduct, the court tightened the standards for both intent and materiality.

As to intent, the court required that “[i]n a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.” *Id.* (emphasis in original). In other words, a party alleging inequitable conduct must prove three things by clear and convincing evidence: 1) the applicant knew of the reference, 2) the applicant knew the reference was material, and 3) the applicant made a deliberate decision to withhold it. The court explicitly rejected the notion that a specific intent to deceive can be proven merely by showing that an applicant knew of a reference, *should have known* it was material, and decided not to submit it.

The Federal Circuit also rejected the notion that a determination of intent can spring from a determination of materiality. Both the use of a “sliding scale” of intent and materiality and an inference of intent from a determination of sufficiently high materiality were explicitly rejected.

There remains a possibility of showing intent to deceive by way of indirect and circumstantial evidence, but an accused infringer must prove that a specific intent to infringe is the *single most reasonable inference* to be drawn from the evidence. In other words, “when there are multiple reasonable inferences that may be drawn, intent to deceive *cannot be found.*” *Id.* at 26 (emphasis added).

As to materiality, the Federal Circuit explained that it previously had raised the intent standard in an effort to “reduce the number of inequitable conduct cases and that this approach “did not cure the problem of overdisclosure of marginally relevant prior art to the PTO.” *Id.* at 26. Thus, to further address the issue of overdisclosure, the court also raised the standard for materiality to a but-for standard.

As a general matter, prior art is material “if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Id.* at 27. In making this determination, courts are to apply the preponderance of the evidence standard and give claims their broadest reasonable construction. Because inequitable conduct is an equitable doctrine hinging on fairness, such a doctrine should only apply “in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” *Id.* at 28.

The court recognized an exception to the but-for standard in the case of “affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit...” *Id.* at 29. By treating such misconduct as material, the court intended to strike a balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.

The Federal Circuit firmly rejected the use of PTO Rule 56 in determining materiality, finding it overbroad in many regards. The court explicitly held that information will not necessarily be material merely because it either: 1) establishes a prima facie case of unpatentability or 2) refutes or is inconsistent with a position taken by the applicant in opposing an argument of unpatentability or asserting an argument of patentability.

Applying these new standards, the district court in this case found materiality based on PTO Rule 56 not on the but-for materiality standard. The district court also found intent to deceive based on a should have known as opposed to the knowing and deliberate standard. Accordingly, the court remanded for the district court to reconsider in light of the standards set forth in this opinion.

Judge O’Malley concurred-in-part, agreeing with the underlying rationale of the decision and with the intent standards, and dissented-in-part as to the materiality standards set forth. Rather, she proposes to overrule those cases which render all claims of a wrongly procured patent unenforceable and suggests that “in the exercise of its discretion, a district court may choose to render fewer than all claims unenforceable, may simply dismiss the action before it, or may fashion some other reasonable remedy, so long as the remedy imposed by the court is commensurate with the violation.” Concurrence at 7. The materiality standard suggested by Judge O’Malley would include conduct where 1) but for the conduct the patent would not have issued; 2) the conduct constitutes a false or misleading representation of fact; or 3) the district court finds that the behavior undermines the integrity of the PTO. *Id.* at 9. She agrees with the majority that Rule 56 is overbroad and district courts should not be directed to rely on it to determine materiality.

Judge Bryson dissented, joined by Judges Gajarsa, Dyk and Prost. The dissenting opinion supports the majority on the issues of intent and the holding that intent and materiality must be proven separately, disagreeing only on the proper standard to apply in determining materiality. The dissenting opinion would continue to rely on PTO Rule 56.

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