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Federal Circuit Changes Inequitable Conduct Standard in Patent Litigation

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In a long-awaited *en banc* decision, the Federal Circuit has greatly raised the already-high standards for establishing that a patent is unenforceable due to inequitable conduct. (*Therasense v. Becton, Dickinson & Co.*, Fed. Cir. No. 2008-1511, May 25, 2011). The Court held that prior art is not "material" for the purposes of establishing inequitable conduct unless "the PTO would not have allowed a claim had it been aware of the undisclosed prior art." And the Federal Circuit held that "a court must weigh the evidence of intent to deceive independent of its analysis of materiality," discontinuing the practice of weighing intent and materiality on a "sliding scale" where a particularly strong showing of materiality would permit a finding of inequitable conduct with less evidence of deceptive intent, and vice versa.

These changes to the law reflect a significant shift in policy. According to the Court, the previous standards, which had been intended to "foster full disclosure to the PTO," had led to "numerous unforeseen and unintended consequences." As a result, the Court determined it necessary to "redirect a doctrine that has been overused to the detriment of the public."

The most significant change is the new "but for" standard for materiality. In holding that a prior art reference is not material unless there is clear and convincing evidence that a claim would not have been allowed "but for" the decision to withhold the reference, the Court rejected the use in court of the broader PTO Rule 56. The Court points out that it is not necessarily the case that a prior art reference will have to support a finding of invalidity in court to be deemed "material" for the purposes of the new standard,

because courts apply the heightened "clear and convincing" standard for invalidity determinations while the PTO applies lower standards, and because the PTO generally applies a "broadest reasonable construction" standard for claim construction. Nevertheless, the new standard is substantially higher than the previous standard, which had been based on PTO Rule 56.

The "but for" standard for materiality will be set aside in cases of "affirmative egregious conduct." Though it did not provide a definition of "affirmative egregious conduct," the Court distinguished the acts of deceiving the PTO with a falsehood from deceiving the PTO with an omission. Affirmative egregious conduct includes "the filing of an unmistakably false affidavit." It does not include "mere nondisclosure of prior art references." The Court reasoned that this exception to the "but for" standard is consistent with the original Supreme Court inequitable conduct cases, which involved "deliberately planned and carefully executed schemes to defraud the PTO and the courts."

The Court also emphasized that inequitable conduct requires proof of specific intent to deceive the PTO: "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 obvious and apparent materiality of a reference, alone, can no longer support a finding of specific intent to deceive: there must be independent evidence that demonstrates the applicant's deceptive intent. Where indirect or circumstantial evidence is employed, deceitful intent must be "the single most reasonable inference able to be drawn from the evidence."

In addition to these changes to the standards for materiality and intent, the majority opinion (joined by six members), concurrence (one member), and dissent (four members) include numerous statements confirming the "broad consensus that the law of inequitable conduct [has been] in an unsatisfactory state." (Dissent). The majority reiterates the rule that, even after an accused infringer demonstrates materiality and deceptive intent, "the district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable." In light of the universal condemnation by the judges of the Federal Circuit of the broad use in litigation of the inequitable conduct defense, it will now be more difficult to demonstrate that the equities weigh in favor of rendering patents unenforceable.

Click [here](#) to read the *Therasense* opinions.