

## Federal Circuit Ruling on Inequitable Conduct Adopts Tougher Standard

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In *Therasense v. Becton Dickinson*, a split Federal Circuit sitting *en banc* adopted a more difficult standard for proving inequitable conduct before the U.S. Patent Office (PTO). The initial panel decision in *Therasense* affirmed the district court ruling, which held that an affidavit from a related application that was not disclosed by the applicant during prosecution was material under the PTO rules, and that the applicant's failure to disclose that material affidavit was intentional. In the *en banc* decision, however, the Federal Circuit held that a party asserting inequitable conduct must establish by a preponderance of the evidence, giving claims their broadest possible reasonable construction, that the PTO would not have allowed a claim but-for any undisclosed reference that can be shown was intentionally withheld from the examiner. The Federal Circuit sitting *en banc* also affirmed the decision in *Star Scientific*, *i.e.*, that the party attempting to establish inequitable conduct must show that the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." The materiality standard of *Therasense* will likely be more difficult to establish than the previous materiality standard. Previously, a party charging inequitable conduct was required to establish that an omitted reference would have been important to a reasonable examiner. Under *Therasense*, it is now necessary to prove that the omitted prior art was dispositive to the examiner's decision to allow a claim.

The Federal Circuit adopted this stricter standard to stem what the majority (and many observers) consider to be the overuse of inequitable conduct as a defense in patent infringement litigation. The majority believed that the inequitable conduct defense has impeded settlements and burdened the courts. To offset the corresponding hardship imposed on accused infringers under the new standard, the Court created an exception for "egregious" conduct, such as submission of an unmistakably false affidavit. However, in cases that do not involve affidavit evidence during prosecution, it may be difficult to demonstrate that conduct was "egregious." When combined with the strict standard for intent, the higher standard for materiality will likely mean that inequitable conduct will be far harder to establish. But it remains to be seen whether this combination will reduce the use of inequitable conduct as an affirmative defense in patent cases or increase the success rate of summary judgment motions filed by patentees challenging inequitable conduct allegations.

One important observation from the *en banc* decision in *Therasense* is that the Court split 6-1-4, which is generally considered to be an indicator that the Supreme Court might review the case. The appellee has indicated it will petition for certification to the Supreme Court, but given that it prevailed below on non-infringement and invalidity, appealing to the Supreme Court would appear to be unnecessary. As such, the new standard for inequitable conduct under *Therasense* might stand for the foreseeable future.