



Federal Circuit Grants En Banc Review of *Therasense v. Becton Dickinson* to Resolve Inequitable Conduct Issues

07.08.2010

Inequitable conduct is asserted as a defense in the vast majority of patent infringement suits and generally involves an allegation that the patentee failed to disclose material information (i.e., prior art) to or intentionally misled the Examiner during the prosecution of the patent application.

Therasense v. Becton Dickinson addresses inequitable conduct during patent prosecution. In *Therasense*, the patentee was accused of making conflicting statements concerning certain prior art to the United States Patent & Trademark Office (PTO) and the European Patent Office (EPO). The patentee told the PTO that a certain element was required but had told the EPO that the same element was optional. The district court ruled that the conflicting statements were material and found that there was intent to deceive the PTO in not disclosing the prior statement made to the EPO. The Court of Appeals for the Federal Circuit agreed, finding no clear errors in the district court's ruling regarding materiality and intent. *Therasense* then petitioned for an *en banc* rehearing, which was granted by the Federal Circuit.

The last time the Federal Circuit addressed inequitable conduct *en banc* was in *Kingsdown v. Hollister*, 863 F.2d 867 (Fed. Cir. 1988). The court there held that inequitable conduct requires that materiality and deceptive intent be separately proven under a clear and convincing standard. Over the last twenty plus years district courts and the Federal Circuit have been criticized for inconsistent application of *Kingsdown*, leading to what has been characterized as a "plague" of inequitable conduct allegations in almost all patent infringement suits. *Burlington Industries, Inc. v. Dayco Corporation*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

Most agree that a clear, firm rule that can be applied consistently should replace the current standard. To that end, the parties in *Therasense* and *amici curiae* have been asked by the court in the Order granting a rehearing en banc to brief the following issues:

- Should the materiality/intent test be modified or replaced?
- If so, should the test be tied more directly to fraud or unclean hands?
- What is the proper standard for materiality ? must alleged misconduct negate one or more claims ? and, what role should PTO rules have in defining materiality?
- Can intent be inferred from materiality?
- Should the materiality/intent test be abandoned?
- Can inequitable conduct materiality/intent standards in other federal agency contexts be applied in the patent context?

Many contend that confusion arises when intent is inferred from materiality. Indeed, Judge Linn penned a vigorous dissent in the vacated panel opinion in *Therasense* in which he argued that the majority erred by failing to recognize that intent to deceive is a subjective standard rather than an objective standard.

Another major question that is yet to be settled is whether the alleged misconduct actually affects the validity of the patent. In other words, is the alleged misconduct only material if it would have changed the outcome of the PTO's decision to grant the patent? Inequitable conduct is grounded in equity. Perhaps not all inequitable conduct, even if proven, should render a patent unenforceable.

Many would also like to see enhanced provisions for attorney fees when inequitable conduct claims are unsuccessful, especially because a charge of inequitable conduct carries an implication of wrongdoing.

The case is scheduled to be heard later this summer.

Discussion of the case can be found at [PatentlyO](#) and [PatentDocs](#) (with a link to the briefing schedule).

Related People

- Thomas F. Bergert ? 434.951.5710 ? tbergert@williamsmullen.com
- Patrick R. Hanes ? 804.420.6455 ? phanes@williamsmullen.com