

# MUIRHEAD AND SATURNELLI, LLC

*Specializing in Intellectual Property Law*

*IP FLASH*

## FEDERAL CIRCUIT TIGHTENS STANDARDS FOR INEQUITABLE CONDUCT BASED ON NONDISCLOSURE OF PRIOR ART

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) has tightened the standards for establishing inequitable conduct based on nondisclosure of prior art to the U.S. Patent and Trademark Office (PTO) in *Therasense, Inc. v. Becton, Dickinson and Co.*, 99 USPQ2d 1065 (Fed. Cir. 2011). Inequitable conduct requires proving by clear and convincing evidence that an applicant intended to deceive the PTO by failing to disclose material prior art during prosecution of a patent application. Under the tightened standards set forth by the Federal Circuit, an intent to deceive requires "that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it," and materiality requires a "but-for" materiality analysis showing that the PTO "would not have allowed a claim had it been aware of the undisclosed prior art."

Inequitable conduct is a defense often raised by an accused infringer in patent infringement litigation that, if proved, bars enforcement of a patent. The Federal Circuit has recognized that the expansion and overuse of the inequitable conduct doctrine has increased "the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost." With *Therasense*, the Federal Circuit "now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."

In *Therasense*, the facts at issue involved a patentability argument set forth by the applicant during prosecution before the European Patent Office (EPO) that was inconsistent with applicant's arguments during prosecution of a corresponding application before the PTO. The district court held the resulting patent unenforceable for inequitable conduct, finding that the EPO arguments were material under the PTO's Rule 56 (37 C.F.R. §1.56) and that an intent to deceive existed based on the absence of a good faith explanation provided by the patentee for failing to disclose the EPO arguments to the PTO. The Federal Circuit in *Therasense* vacated the district court's decision on both the intent to deceive and materiality requirements and remanded the decision for further determinations according to the tightened standards now set forth by the Federal Circuit.

Under the Federal Circuit's tightened standards, establishing an intent to deceive requires that "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." Intent may not be inferred solely from materiality of undisclosed prior art. Intent may be inferred from indirect evidence but must be "the single most reasonable inference able to be drawn from the evidence." Moreover, "[p]roving 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." Materiality requires a "but-for" materiality analysis. That is, undisclosed prior art is "but-for" material only if the PTO "would not have allowed a claim had it been aware of the undisclosed prior art." One exception to "but-for" materiality is for cases of affirmative egregious misconduct in which an applicant "deliberately planned and carefully executed scheme[s]" to defraud the PTO and the courts. Filing an "unmistakably false" affidavit is one example of an affirmative act of egregious misconduct that is considered to be material.

It is noted that the Federal Circuit has rejected the definition of materiality that is set forth in PTO Rule 56 as failing to include "but-for" materiality. Current Rule 56 provides that information is material if it is not cumulative of prior art already of record and establishes a *prima facie* case of unpatentability or refutes, or is inconsistent with, a position taken by applicant opposing an argument for unpatentability relied on by the PTO or asserting an argument of patentability. Although no clarifications have yet been issued, the PTO has stated that it expects to issue revised materiality guidelines in view of *Therasense*.

This IP Flash is being provided for information purposes only and should not be construed as legal advice or legal opinion.

200 Friberg Parkway, Suite 1001  
Westborough, MA 01581  
(508) 898-8601 • Fax (508) 898-8602 • [www.westboro-ip.com](http://www.westboro-ip.com)