Federal Circuit Establishes New Standard for Inequitable Conduct

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On May 25, 2011 the Federal Circuit released its en banc decision in ***Theresense, Inc. v. Becton, Dickinson & Co.*** , in which the Court articulated the appropriate standard for inequitable conduct before the PTO. The majority wrote, "[t]his court 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."

Majority

At issue in the district court was the 5,820,551 patent which involved disposable blood glucose test strips for diabetes management. Protective membranes are often used on such glucose test strips to protect the veracity of the results. The '551 patent disclosed a test unit without a protective membrane. The Examiner cited the 4,545,382 patent, also held by Abbott, as disclosing a unit which could be used without a membrane. A declaration and affidavit was submitted explaining the language of the '382 patent would not encourage one of ordinary skill in the art to use the device without a membrane, and the Examiner relied upon the statements for allowance of the '551 patent. It came to light during litigation that Abbott had previously made representations to the European Patent Office that, in fact, "[the] disclosure was unequivocally clear:" the membrane of the '382 patent was optional. At the district court level, claims 1–4 of the '551 patent were held invalid as obvious and the '551 patent was held unenforceable due to inequitable conduct.

The majority undertook a discussion of the *Keystone*, *Hazel-Atlas*, and *Precision* cases which set forth the test for unclean hands, the precursor to inequitable conduct. The Court continued, discussing the ways in which the inequitable conduct doctrine diverged from these original cases, expanding to include a broader scope of misconduct—"mere non-disclosure" to the PTO—and by adopting a more potent remedy—unenforceability of the entire patent. This lead to the sliding scale test, the "reasonable examiner standard" and the standards articulated in 37 C.F.R. 1.56.

The Court continued, noting that these standards lack uniformity and encourage the use of the "atomic bomb" of patent law. "Left unfettered, the inequitable conduct doctrine has plagued not only the courts but

also the entire patent system." The court then proceeded to "tighten the standard." For purposes of the intent prong, the Court held, "the accused infringer must show the patentee acted with the specific intent to deceive the PTO." This requires "clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference." No longer will the "should have known" analysis satisfy this standard. Finally, the absence of a good faith explanation does not, by itself, prove the intent to deceive. With respect to the materiality prong, the Court articulated a "but for" materiality standard. Thus, "when an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." Important to note, the decision articulates a preponderance of the evidence standard for the "but for" test, which is different than the clear and convincing evidence standard required for invalidity. Finally the court notes an exception to the "but for" test—in cases of "affirmative egregious misconduct," the materiality prong may also be satisfied. The Court vacated the finding of materiality at the district court and remanded for application of the new test:

1. Intent: clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.
2. Materiality: preponderance of the evidence must show that the PTO would not have allowed a claim had it been aware of the undisclosed prior art—"but for" test.
a. Exception: affirmative egregious misconduct.

Concurrence

The concurring opinion criticizes both the majority and the dissent for as sacrificing flexibility for rigidity. The concurrence agrees with the majorities overall holding, but wishes to respect the equitable nature of the test. This means leaving the decision of inequitable conduct to the decision of the lower courts. The opinion notes this would help in the instance there is some intentional misconduct which does not fit within the rigid test, yet still warrants equitable relief. This includes allowing the district court to "fashion some other reasonable remedy, so long as the remedy imposed by the court is 'commensurate with the violation.'" The concurrence articulates a materiality test including:

1. But for the conduct (whether it be in the form of affirmative act or intentional non-disclosure), the patent would not have issued (as Chief Judge Rader explains in the majority opinion);
2. The conduct constitutes a false or misleading representation of fact (rendered so either because the statement made is false on its face or information is omitted which, if known, would render the

representation false or misleading), or
3. The district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined.

Dissent

The dissent begins by noting that the "specific intent," as articulated by the majority and the clear and convincing evidence standard. The disagreement revolves around the materiality standard. The dissent would prefer to continue to apply the standard as articulated in 37 C.F.R. 1.56 because "[f]irst, examiners need to conduct effective and efficient examinations, i.e., what information is material to the examination process. Second, the higher standard of materiality adopted by the majority will not provide appropriate incentives for patent applicants to comply with the disclosure obligation the PTO places on them." Essentially, the dissent would re-affirm the standard articulated in *Kingsdown Medical*. The test from the dissent would require:

1. Inequitable conduct requires proof, by clear and convincing evidence, that the applicant or attorney intended to misled the PTO with respect to the material matter.
2. Materiality is measured by what the PTO demands of those who apply for and prosecute patent applications. The disclosure standard for the PTO expects those parties to comply with is set forth in the current version of the PTO's Rule 56. Under that standard, inequitable conduct requires proof that the information at issue either established, by itself or in combination with other information, a prima facie case of unpatentability, or was inconsistent with a position taken by the applicant before the PTO with respect to patentability.
3. Intent to mislead and materiality must be separately proved. There is no "sliding scale" under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue.

The dissent continues, describing the veracity of such a test for policy reasons and for reasons of deference to the PTO. Further, the dissent articulates this standard as more historically accurate with the *Keystone*, *Hazel-Atlas*, and *Precision* cases. The dissent describes the majority test as "Draconian" and inappropriate within the context of history, precedent, and the public policy consideration of the inequitable conduct doctrine.

For the full opinion, click **here** .