

Therasense v. Becton, Dickinson & Co.:
The Federal Circuit Modifies the Inequitable Conduct Standard

In *Therasense*, the Federal Circuit attempted to alleviate the judicially-created “plague” of inequitable conduct by focusing the diluted standards of intent and materiality. In doing so, the Court significantly changed the law of inequitable conduct. However, it remains to be seen whether the new standards set forth in *Therasense* will promote the majority’s policy of reducing claims of inequitable conduct by patent litigators and/or encouraging more efficient patent prosecution at the PTO.

During prosecution of a patent application, a patentee and his or her representatives have a duty of candor and good faith to the PTO to disclose all material references for which the patentee has knowledge. If a patentee fails to satisfy his or her duty and later asserts the patent, an accused infringer can assert the defense of inequitable conduct. A finding that any claim of the patent was obtained through inequitable conduct results in the entire patent being unenforceable.

To prevail on the defense of inequitable conduct, an accused infringer must prove by clear and convincing evidence that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. However, as the Court acknowledged in *Therasense*, “the standards for intent to deceive and materiality have fluctuated over time.” Indeed, the intent standard was often satisfied by negligence alone (the “knew or should have known” test), and the materiality standard was diluted to a reasonable examiner standard (*i.e.*, a reference was material if there was “a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent”).

Intent

In *Therasense*, the Court set forth a heightened intent standard, holding that in order to prove that the patentee acted with the specific intent to deceive the PTO, the “accused infringer must prove by clear and convincing evidence that: (1) the applicant knew of the reference; (2) knew that it was material; and (3) made a deliberate decision to withhold it.” Accordingly, the ‘knew or should have known’ test no longer satisfies the intent standard.

The Court did acknowledge that “[b]ecause direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.” However, the Court went on to say, to meet the clear and convincing standard the evidence “must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances” (emphasis in the original).

In support of its new intent standard, the Federal Circuit cited three early Supreme Court cases – *Precision*, *Hazel-Atlas*, and *Keystone* – from which the judge-made doctrine of inequitable conduct had evolved. The Court noted that each of these cases “dealt with particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence” and “involved deliberately planned and carefully executed schemes to defraud not only the PTO but also the courts,” thereby providing further vigor to the heightened intent standard.

Materiality

The Federal Circuit also modified the materiality standard, holding that “the materiality required to establish inequitable conduct is but-for materiality.” If an applicant fails to disclose prior art to the PTO, the prior art is only but-for material if the PTO would not have allowed a claim had it been aware of the prior art.

Notably, the Court held that rather than the clear and convincing evidentiary standard, the materiality prong can be proven using the PTO’s evidentiary standards (e.g., preponderance of the evidence), since the relevant inquiry is whether the PTO would have allowed the claim if it had been aware of the reference.

Lastly, the Court held that “[a]lthough but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, this court recognizes an exception in cases of affirmative egregious misconduct.” For example (and apparently not limited to this example), the submission of “an unmistakably false affidavit” is undeniably material, and was likely submitted because the patentee believed the falsehood would affect issuance of the patent. Time will tell whether this exception might be an open door through which the “plague” of inequitable conduct charges survives unscathed.

The Sliding Scale

The Court further held that “[i]ntent and materiality are separate requirements.” Accordingly, courts can no longer use a sliding scale where weak evidence of intent is saved by strong evidence of materiality, and vice versa. Thus, for example, a clear finding of specific intent to deceive the PTO is not sufficient grounds for a finding of inequitable conduct unless the withheld reference is also found to be material, and vice versa.

Accordingly, evidence of intent to deceive must be weighed independently from the analysis of materiality. After all, the Court noted, “the patentee obtains no advantage from misconduct if the patent would have issued anyway.”

Inequitable Conduct Post-*Therasense*

As with all Federal Circuit decisions, it is not immediately clear how the changes will affect patent prosecutors or litigators.

In light of the heightened standards, it would appear that fewer accused infringers will be able to successfully establish the inequitable conduct defense. Accordingly, patent litigators should carefully assess inequitable conduct claims in light of the new standard before asserting the defense, taking special care to review the materiality of any non-disclosed reference and the strength of any circumstantial evidence of the patentee’s intent to deceive.

Therasense may not, however, have a dramatic effect on patent prosecutors. Patent prosecutors will continue to make daily decisions about which references to submit to the PTO, and may later be found to have acted with specific intent to deceive – regardless of their actual intent – if a court finds that a prior art reference they intentionally omitted was material. Accordingly, the holding of *Therasense* may do little to address the number of superfluous references submitted to the PTO by diligent patent prosecutors attempting to satisfy their duty to disclose and avoid the “atomic bomb” of inequitable conduct.

If you have any questions, please contact George R. McGuire, Chair, Intellectual Property Practice Group, at 315.218.8515 or gmcguire@bsk.com.