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Patent and Trademark Office Proposes Amendments to Prosecution Rules to Address Inequitable Conduct Standard Announced in Recent *Therasense* Opinion

The U.S. Patent and Trademark Office (USPTO) recently proposed amendments to its rules of practice that impact the conduct of applicants and their counsel in efforts to secure patents. Specifically, on July 21, 2011, the USPTO published notice in the *Federal Register* of proposed amendments to incorporate its reading of *Therasense Inc. v. Becton, Dickinson & Co.*, decided *en banc* by the U.S. Court of Appeals for the Federal Circuit in May of this year. The notice seeks comment on the proposed amendments by September 19, 2011.

In *Therasense*, the court addressed the proper standard for finding an issued U.S. patent unenforceable due to inequitable conduct of the applicant during its prosecution before the USPTO. The court held that the standard for showing materiality required to establish inequitable conduct, as a general matter, is “but for” materiality — that is, the patent would not have been issued but for the applicant's failure to disclose the omitted or undisclosed prior art to the examiner during prosecution. The court recognized an exception to this extremely high standard for “affirmative egregious misconduct” of the applicant.

Now, the USPTO proposes to amend 37 C.F.R. 1.56(b) to harmonize its rules of practice with the standard set forth in *Therasense* as follows:

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1. Information is material to patentability if it is material under the standard set forth in *Therasense, Inc. v. Becton, Dickinson & Co.*, ___ F.3d ___ (Fed. Cir. 2011).
2. Information is material to patentability under *Therasense* if:
 - a. The USPTO would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or
 - b. The applicant engages in affirmative egregious misconduct before the USPTO as to the information.

The USPTO's *Federal Register* notice points out that mere nondisclosures or failures to mention information would not constitute affirmative egregious misconduct, and that the USPTO will not treat information disclosures as admissions of unpatentability for any claims in the application.

The proposal would also make changes to Section 1.555(b) for *ex parte* and *inter partes* reexamination proceedings, adopting the same "but for" standard for materiality.

Contact Info

If you have any questions about the proposed rule amendments or would like to discuss possible comments to the USPTO regarding its proposed rule changes, please contact your Husch Blackwell attorney or one of the attorneys listed below.

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