

# PATENT AND TRADEMARK OFFICE PROPOSES REVISED DUTY-TO-DISCLOSE STANDARD

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Inequitable conduct is found where a patent applicant breaches his or her duty of candor and good faith to the U.S. Patent and Trademark Office (USPTO) while applying for a patent. If proven, this equitable defense to patent infringement bars enforcement of the patent—a remedy that Chief Judge Rader of the Federal Circuit dubbed the “atomic bomb” of patent law. Inequitable conduct may be found where an applicant misrepresented or failed to disclose a material prior art reference with the intent to deceive the USPTO.

Inequitable conduct has become a standard defense raised by accused infringers, creating uncertainty and added expense in patent litigation and causing patent applicants to drown the USPTO in a flood of marginally relevant prior art references. However, in its recent *en banc* decision *Therasense, Inc. v. Becton, Dickinson & Co.*, 99 U.S.P.Q.2d 1065 (Fed. Cir. 2011), the Federal Circuit raised the standard for establishing inequitable conduct. The Federal Circuit now requires an accused infringer show but-for materiality: “[w]hen an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the [USPTO] would not have allowed a claim had it been aware of the undisclosed prior art.”

In response to the *Therasense* decision, the USPTO released a notice of proposed rulemaking (NPRM) requesting comment on revisions to the duty-to-disclose standard under USPTO Rule 56, 37 C.F.R. § 1.56. The proposed revision to section 1.56 reads:

§ 1.56 Duty to disclose information material to patentability.

\* \* \* \* \*

(b) Information is material to patentability if it is material under the standard set forth in [Therasense]. Information is material to patentability under Therasense if:

- (1) The Office 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
- (2) The applicant engages in affirmative egregious misconduct.

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The USPTO refers to the proposed standard as a but-for-plus standard—the “plus” originating from part (b)(2), which is aimed at preventing acts such as the filing of an unmistakably false affidavit. Under the proposed rule, the mere failure to disclose information will not be considered material to patentability if the pending claim would be allowable in light of that information. The USPTO “recognizes the tension inherent in a disclosure standard based on unpatentability, but appreciates and expects that patent applicants are inclined to be forthcoming and submit information beyond that required by proposed Rule 56, in an effort to assist examiners in performing their duties.”

The NPRM seeks comment on whether incentives should be created for applicants to explain or clarify the relationship between prior art and the claimed invention beyond the Therasense standard. The USPTO believes such incentives would encourage applicants to submit information beyond what is required under Therasense for the purpose of advancing prosecution.

Comments on the proposed rule change must be submitted to the USPTO by September 19, 2011. However, the USPTO acknowledges that the Supreme Court may still weigh in on the case, which could delay promulgation of a final rule.