

Conformity is a Virtue: The U.S. Patent and Trademark Office Proposes Changes to the Duty of Disclosure to Match the *Therasense* Standard

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PRACTICES Patents, Patent Prosecution and Counseling, Intellectual Property

The U.S. Patent and Trademark Office (PTO) has proposed changes to two rules that are designed to streamline the obligations of innovators and their patent practitioners to disclose information to the PTO in patent applications and reexamination proceedings.

The proposed rules would modify the standard used to determine what information is material to patentability and therefore must be provided to the PTO to satisfy the duty of disclosure. Specifically, the PTO has proposed to change the duty of disclosure materiality standard to conform to the inequitable conduct materiality standard set forth in the Federal Circuit's recent decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, ___ F.3d ___, 2011 U.S. App. LEXIS 10590 (Fed. Cir. 2011) (*en banc*).

In *Therasense*, the Federal Circuit articulated a "but-for-plus" materiality standard for establishing inequitable conduct. As to the "but-for" portion of the standard, the Federal Circuit explained that "[w]hen 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." *Therasense*, 2011 U.S. App. LEXIS 10590, at *37. The Federal Circuit further explained: "in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference" and "should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." *Id.*

As for the "plus" portion of the standard, the Federal Circuit recognized that affirmative acts of egregious misconduct require special consideration. In this regard, the Federal Circuit explained: "Although 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" and that "a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent." *Id.*, at *39-40.

The Federal Circuit provided several examples to help clarify the "plus" portion of the standard: (1) "the mere nondisclosure of prior art references to the PTO *would not* constitute affirmative egregious misconduct; (2) "the failure to mention prior art references in an affidavit *would not* constitute affirmative egregious misconduct; and (3) "the submission of an unmistakably false affidavit *would* constitute affirmative egregious misconduct." *Id.*, at *39-41.

Under the proposed rule changes, the PTO would use this "but-for-plus" standard to determine whether information is material and therefore must be submitted to the PTO to satisfy the duty of disclosure. If adopted, the "but-for-plus" standard would replace the current duty of disclosure materiality standard set forth in 37 C.F.R. §§ 1.56(b) and 1.555(b) that requires patent applicants and others substantively involved in the prosecution to provide information that: (1) "establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) "refutes, or is inconsistent with, a position the patent applicant (or patent owner) takes in

opposing an argument of unpatentability relied on by the PTO or asserting an argument of patentability.

With regard to patent applications, 37 C.F.R. ? 1.56(b) would be amended to read as follows:

? 1.56 Duty to disclose information material to patentability.
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(b) 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). 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 before the Office as to the information.

With regard to reexaminations, 37 C.F.R. ? 1.555(b) would be similarly amended.

The PTO expects that applying the same standard to the duty of disclosure and the establishment of inequitable conduct will simplify compliance and prevent patent applicants from being put in the position of having to meet one standard for materiality, as defined in *Therasense* in defending against inequitable conduct allegations, and a second different materiality standard to fulfill the present duty of disclosure before the PTO. The PTO also expects that this will result in a reduction in the quantity of cited references, which could help streamline prosecution timing.

The PTO recognizes that *Therasense* may be subject to further review by the U.S. Supreme Court. However, the PTO is currently promulgating these proposed changes in parallel with any possible appeal to the Supreme Court so that the PTO may receive and consider public comments in a timely manner. Issuance of any final rules could be delayed pending Supreme Court review of the *Therasense* decision.

The PTO is also considering other unspecified actions that may provide an incentive for patent applicants to assist the PTO by explaining or clarifying the relationship of prior art to claimed inventions. From a practical standpoint, this rule change clearly moves the fuzzy line away from requiring submissions that may or may not be material to patentability, but there is still no clear safe harbor guiding innovators and patent practitioners around the rocky shoals of what is material and when it is safe not to submit a relevant reference of which they are aware. The PTO is accepting written public comments regarding the proposed rule changes until September 19, 2011. No public hearing will be held.

If you have any questions regarding these matters, please contact one of our patent attorneys. **You may also view the alert in the PDF linked below.**

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