



## **ARE Patent Litigation Alert: USPTO Proposes to Revise the Materiality Standard for the Duty to Disclose to Conform with the *Therasense***

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Yesterday, the United States Patent and Trademark Office (“USPTO”) proposed to revise the standard for materiality in the duty to disclose information during the prosecution of patents in light of the Federal Circuit’s decision in *Therasense, Inc. v. Becton, Dickinson & Co*, Nos. 208-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011)(en banc). Specifically, the USPTO is proposing to harmonize the materiality standard of the USPTO rules with that defined in *Therasense* in connection with the inequitable conduct doctrine.

In *Therasense*, in the context of evaluating the standard for inequitable conduct, the Federal Circuit defined materiality using a “but-for-plus” standard: “[I]n 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.” *Id.* at \*11. The *Therasense* Court also recognized an exception to this materiality prong for cases of “affirmative egregious misconduct.” *Id.* at \*12.

The USPTO’s proposed rulemaking is to revise the materiality standard for the duty to disclose information to the USPTO in patent applications and reexamination proceedings set forth in §§ 1.56(b) and 1.555(b) at Title 37 Part 1 of the Code of Federal Regulations in light of the above standard defined by the Federal Circuit in *Therasense*.

Under the newly proposed rule adopting the *Therasense* standard, information is material to patentability if: (1) The USPTO would not allow a claim if it were aware of the information, giving the claim its broadest reasonable construction; or (2) The applicant engages in affirmative egregious misconduct before the USPTO with respect to the information.

In its notice of proposed rule making, the USPTO indicated that “[t]he materiality standard set forth in *Therasense* should reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, consequently reducing the incentive to submit information disclosure statements containing marginally relevant information and enabling applicant to be more forthcoming and helpful to the Office.” Revision of the Materiality to Patentability



Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43, 631 (proposed July 21, 2011). The USPTO noted that while the *Therasense* standard is not as inclusive as the current § 1.56(b), the USPTO expects that the “but-for-plus” standard of *Therasense* will result in patent applicants providing the most relevant information. The USPTO also indicated that this standard “should also continue to prevent fraud on the Office and other egregious forms of misconduct.” *Id.* Finally the USPTO indicated that while a harmonized standard for materiality is not required, it would be simpler for the patent system to have a harmonized standard as between the Federal Courts and the USPTO.

Interestingly, in its prior Amicus Brief and in oral argument at the Federal Circuit in the *Therasense* case, the USPTO had argued in favor of the current version of Rule 1.56 as the standard for materiality and against the “but-for-plus” test.

In connection with this notice of proposed rule making, the USPTO is soliciting comments from the public, which must be received by September 19, 2011. However, the USPTO stated that if a petition for *certiorari* is filed and the Supreme Court grants review of the *Therasense* case, the USPTO would consider delaying the issuance of a final rule until the Supreme Court has resolved this issue. The parties still have until August 23, 2011 to decide whether to file for appeal by *certiorari* to the Supreme Court if the deadline is not extended.

Finally, the USPTO also indicated that it is considering additional ways to encourage applicants to submit information that would be helpful and useful in advancing patent examination beyond that required under the *Therasense* materiality standard.

For more information on these developments, please contact one of our attorneys.

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