Patent Law Update: The US PTO Proposes to Adopt Therasense Materiality Standard for Practice in the US PTO

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The US PTO Proposes to Adopt *Therasense* Materiality Standard for Practice in the US PTO

The US PTO has acquiesced to the recent decision of the Federal Circuit Court of Appeals in *Therasense v. Becton-Dickinson,* proposing that it will adopt the *Therasense* standard of materiality for disclosure of information by applicants in US patent prosecution. See Federal Register Vol. 76, No. 140/Thursday, July 21, 2011/Proposed Rules 43631. This would narrow Rule 56, 37 CFR 1.56, to read as follows:

(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.

(37 CFR 1.555 is also to be amended to the same language.)

The PTO does not include in the proposed rule, but states in its notice of proposed rulemaking, that "as stated in *Therasense,* neither mere nondisclosure of information to the Office nor failure to mention information in an affidavit, declaration or other statement to the Office constitutes affirmative egregious misconduct."

Comments are solicited by the PTO on or before September 19, 2011. The PTO expresses the belief that "a unitary materiality standard" will result in patent applicants providing the most relevant information, reduce the incentive to submit marginally relevant information, and is simpler for the patent bar to implement. As to the possibility of appeal of

Therasense to the U.S. Supreme Court, the PTO states it is proceeding toward a final rule, but with the possibility of delaying the rule in the event of appeal.

Commentary: There are those who filed *amicus* briefs in the *Therasense* case who will be disappointed about the *Therasense* result and the PTO's notice of proposed rulemaking. Some view the narrowing of materiality as having the potential to lead to more non-disclosure of important information, and reduction in the power of the inequitable conduct defense to patent infringement litigation. Others, however, will consider the *Therasense* result and the proposed rule change insufficient to solve what they perceive to be the repeated plague of inequitable conduct allegations. These critics will be dissatisfied that the Office proposes to retain the portion (a) of Rule 56 that states that applicants owe the PTO a duty of candor and good faith that only includes but is not limited to disclosing material information. They will also be troubled by the adoption of a standard of affirmative acts of egregious misconduct, asserting the standard is amorphous and therefore arguably worse than before *Therasense.* The PTO states, however, that it proposes to adopt the *Therasense* standard in part only because of the existence of the affirmative acts "substandard."

Practice tip: Practitioners should be aware that *Therasense* and the proposed rule appear to state a *per se* rule of materiality for affidavits. That is, a false affidavit may now be *per se* material, no matter what the subject of the affidavit is. For example, false small entity affidavits and similar mundane affidavits may be *per se* material, such that the only remaining issue on the way to concluding that associated patents are unenforceable is the intent of those involved with the affidavits. Practitioners would be well advised to exercise extreme caution in preparing and filing affidavits, regardless of how mundane the subject matter of the affidavit. The same caution would be wise as to all acts other than the decision whether to disclose or refrain from disclosing prior art, in that such acts could be characterized as affirmative acts of egregious misconduct.

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