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Sent: Monday, July 25, 2011 10:05 AM
To: 'AC58.comments@uspto.gov'
Subject: Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications

I generally concur with the objective of the proposed amendments to §§ 1.56(b) and 1.555(b) given the Therasense opinion. However, I question the text of the amendments as drafted.

I am unaware of any Patent Rule which specifically references an opinion of the Federal Circuit Court of Appeals, much less any Patent Rule that appears to incorporate an opinion by reference into the rule. I suggest that the rule be revised to remove specific reference to the Therasense opinion. Incorporating an opinion by reference may lead to confusion and ambiguity concerning the scope of the rule. In the comments that follow reference is made to § 1.56(b) for convenience, it being understood that § 1.555(b) is on this point identical.

The draft rule provides that "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."

The draft rule thus provides two alternative statements that: (a) information material under the standard set forth in Therasense is material to patentability, and (b) information meeting the conditions of either subsections (1) or (2) is "material to patentability under Therasense." Are these two alternative statements fully equivalent? For example, is it possible that there is information "material under the standard set forth in Therasense" that does not meet the conditions of either subsections (1) or (2)? If this is the case, then the PTO has effectively incorporated an unstated standard into § 1.56(b). If the two alternative statements are fully equivalent, then why include the reference to Therasense at all? It would be clearer and consistent with accepted style to simply state: "Information is material to patentability 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."

As drafted, the rule will doubtless engender litigation over whether or not the two alternative statements of the standard are equivalent. One party will argue that they met the conditions of both subsections (1) and (2) and thus complied with the duty of disclosure under § 1.56(b), while the other party will argue that there is some further and different materiality standard in Therasense beyond that contained in subsections (1) and (2), and that there was not compliance with the duty of disclosure. The inherent ambiguity in the rule as drafted will have implications not only in litigation, but also in patent prosecution because it is impossible from the rules themselves to ascertain the full scope of the duty of a patent practitioner or applicant with respect to disclosure.

As a matter of drafting style, explicitly incorporating an opinion into a rule is bad form. What happens if after the rule is effective for some reason Therasense is vacated, or is subsequently modified, limited or overruled in part? Does this effect a change in § 1.56(b)? Should an administrative agency, such as PTO, as a matter of policy appear to abrogate its own rule making authority by explicitly referencing a decision of another branch of government? Obviously court opinions define and delimit rule making authority, but court opinions ought not be conflated with rules.

The opinions expressed in this comment are solely my own, and are not to be construed as the opinion of my employer or of any client.

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