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Sent via email to AC58.comments@uspto.gov.

I write in opposition to the proposed amendment to 37 C.F.R. §§ 1.56 and 1.55, as published in 76 Fed. Reg. 43631 (July 21, 2011). The proposed amendment, which would replace the existing definition of materiality with the standard announced in *Therasense, Inc. v. Becton, Dickinson & Co.*, ___ F.3d ___ (Fed. Cir. 2011), is flawed in the following respects:

1. Institutional Deference. The duty to disclose material information, and the standard for materiality, are matters that the PTO should properly determine in connection with ensuring efficient and effective examination of patents. By expressly deferring to the *Therasense* ruling, the PTO would make the Federal Circuit the arbiter of what information the PTO needs in order to do its job. Although this is not, strictly speaking, an instance requiring *Chevron*¹ deference (because the Federal Circuit was interpreting the judicially-created doctrine of inequitable conduct rather than the PTO's interpretation and application of its own regulations), the same general principle applies: courts should defer to administrative agency determinations about how the agency carries out its business, not the other way around.

2. The Rule is Not Self-Applying. With the existing version of Rule 56, a conscientious patent applicant or attorney can apply the rule and make a reasonable determination as to whether an item of prior art falls within the rule. Insofar as it relies on after-the-fact court determinations about (a) what is the broadest reasonable construction, and (b) whether the prior art actually invalidates the claims under that construction, the but-for test announced in

¹ *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Therasense is harder for patent applicants to apply and interpret prospectively, at the time they are deciding what art to disclose to the PTO.

3. Disclosure Becomes a Catch-22. Under the but-for test, the only prior art that must be disclosed is art that invalidates the claims. *A fortiori*, if prior art is disclosed, some pending claim should not issue, and if all the claims should issue, no prior art should be disclosed. The proposed rulemaking acknowledges this as a “tension.” 76 Fed. Reg. at 43633. To resolve this “tension,” the proposed rulemaking makes a promise on behalf of the PTO: “the Office will not regard information disclosures as admissions of unpatentability for any claims in the application.” *Id.* However, the PTO has no authority to make such a promise on behalf of the courts. It is inevitable that, under a but-for test as part of the inequitable conduct doctrine, at least some courts will hold any disclosure of prior art to be an admission that some pending claim in the application is unpatentable. If the PTO changes the duty of disclosure rules to also adopt the but-for test, the odds of courts so ruling will increase substantially.

4. “Affirmative Egregious Misconduct” is Vague and Undefined. Recognizing that not all acts of inequitable conduct will necessarily be based on failures to disclose information that is material under the but-for test, the Federal Circuit in *Therasense* also noted that some—unspecified—acts of affirmative egregious misconduct could also form a basis for inequitable conduct findings. The court, however, left it to future decisions to determine on a case-by-case basis what will constitute such conduct. While such a standard is arguably appropriate in the realm of appellate common-law jurisprudence, it is quite another matter to promulgate a regulation specifying that as the standard of conduct. It is vague and provides no substantive guidance for applicants and their counsel to follow during patent prosecution. Among other things, it is unclear how, if at all, “affirmative egregious misconduct” relates to “disreputable or gross misconduct,” which is governed by 37 C.F.R. § 10.23 (and includes no fewer than nineteen examples of specific types of prohibited conduct). At a minimum, the PTO should allow the term to develop a meaning through case-by-case development in the courts, rather than promulgating it as an indefinite standard of conduct.

5. The Standards For Materiality and Invalidity Are Confusingly Non-Identical. As adopted by the court in *Therasense*, the but-for test holds that information is material if, when the claims in the application are given their broadest reasonable construction, the information would render one or more claims unpatentable, using a preponderance of the evidence test. By contrast, the test for invalidity in patent litigation is whether, using the claim constructions adopted in the *Markman* hearing, the prior art anticipates or renders obvious one or more claims, using a clear and convincing burden of proof. If courts rigorously observe these important distinctions, it will be theoretically possible for prior art to be material but not invalidating. In practice, it is difficult to imagine that courts will consistently, rigorously, observe this distinction. Moreover, on those occasions where a trial court seeks an advisory verdict from the jury on inequitable conduct, the jury will have to be instructed that the claim terms mean one thing for the purpose of determining materiality, and that they mean something else for the purpose of determining invalidity. This may strike some jurors as bizarre.

6. The Stated Rationale For the Amendment Does Not Justify the Rule Change. The proposed rulemaking postulates that “the 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 applicants to be more forthcoming and helpful to the Office.” 76 Fed. Reg. at 43631. However, the frequent use (and arguable overuse) of inequitable conduct in litigation has been due in large part to the courts’ persistence in applying a “reasonable examiner” standard of materiality in combination with an intent standard that contravened the standard announced in the *Kingsdown* case. The 1992 version of Rule 56 has not appreciably contributed to either the problem of overuse in litigation or the problem of over-disclosure to the PTO on information disclosure statements. Therefore, there is no clear need to amend Rule 56.

For each of the foregoing reasons, I respectfully oppose the proposed rulemaking.

Sincerely,

A handwritten signature in black ink, appearing to read 'Christian E. Mammen', written over a horizontal line.

Christian E. Mammen