

September 19, 2011

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**RE: Comments on: “Revision of the Materiality to Patentability Standard
for the Duty to Disclose Information in Patent Applications”
76 Federal Register 43631 (July 21, 2011)**

Dear Under Secretary Kappos:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments in response to the Notice of the U.S. Patent and Trademark Office (USPTO) regarding “Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications.”

AIPLA is a national bar association whose approximately 16,000 members are primarily lawyers and other patent practitioners in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

AIPLA supports the PTO’s efforts to revise the Office’s materiality standard for the duty to disclose to the USPTO, as is set forth in rules 1.56(b) and 1.555(b), to match the materiality standard, as recently defined by the en banc Federal Circuit in *Therasense, Inc. v. Becton, Dickinson, & Co.*, Fed. Cir., en banc, No. 2008-1511, 5/25/2011, for the inequitable conduct doctrine. It is highly desirable to have a single materiality standard for both the inequitable conduct doctrine as it may be raised against a patentee in litigation and the duty to disclose prior art to the Office during prosecution of patent applications and reexamination proceedings.

A single standard will reduce the confusion and inconsistencies that existed before the *Therasense* decision. Irrespective of rules 1.56 and 1.555, many practitioners felt required to submit all information in their possession to the Office because of the varying, and shifting, standards for inequitable conduct indicated by the Federal Circuit in its decisions. AIPLA supports the decision by the Office to adopt the “but-for-plus” standard announced by the Federal Circuit as it provides a single materiality standard for applicants to use. We anticipate, however, that many practitioners will continue to submit as much information as possible in

order to bolster at least the apparent validity of the issued patent. The citation of many relevant references may be seen as increasing the burden on a would-be infringer to invalidate an issued patent over information that, at least on its face, has been considered during examination.

Moreover, as the “but-for-plus” standard has raised the bar and made it more difficult to prove inequitable conduct in the courts, the Office, by adopting the same materiality standard, hopes that there will be less extraneous information submitted via Information Disclosure Statements. This would be beneficial to the Office, as well as to those submitting information to the Office, because any non-material information that is submitted may only clutter up an application file.

While we strongly agree that there should be a single standard for materiality used by both the courts and the Office, we have a few concerns about the text of the rules as presented in the Federal Register Notice.

First, AIPLA believes that the presentation of both the “but for” and the “affirmative egregious misconduct” tests in a single rule may lead to confusion. Rules 1.56(b) and 1.555(b) concern the materiality of information. The affirmative egregious misconduct referred to in the *Therasense* decision, however, is not related to the materiality of information but to the materiality of the misconduct itself. “When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.”¹ Because the affirmative egregious misconduct referred to in rules 1.56(b)(2) and 1.555(b)(2) is conduct, a third party would not be able to submit evidence of it under rule 1.99 as that rule limits submissions to printed publications. It would seem, however, more likely that a third party would be able to provide evidence of such conduct than the patent applicant or patent owner.

Moreover, 37 C.F.R. §§1.56(a) and 1.555(a) already include sanctions for at least some affirmative egregious misconduct. In particular, rule 1.56(a) states, “[h]owever, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.” Similarly, rule 1.555(a) states, “the duties of candor, good faith, and disclosure have not been complied with if any fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct by, or on behalf of, the patent owner in the reexamination proceeding.”

We also note that the misconduct addressed in this part of the *Therasense* decision is the same misconduct covered by 37 C.F.R. § 11.18(b)(i). The main difference is the penalty. In pertinent part, 37 C.F.R. § 11.18(b)(i) states,

whoever ... knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or knowingly and willfully makes any false, fictitious, or fraudulent statements or representations, or knowingly and willfully makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry, shall be subject to the penalties set forth under 18 U.S.C. 1001 and any other applicable criminal statute, and violations of the provisions of this section may jeopardize the probative value of the paper.

¹ 99 USPQ2d 1065, 1074 (Fed. Cir. 2011)

The penalties under 18 U.S.C. §1001 are a fine and imprisonment. While the rule also states that the violation “may jeopardize the probative value of the paper,” this is less than the penalty of rule 1.56 which states that “no patent will be granted.”

We are concerned that the persons who may be found to have committed acts of affirmative egregious misconduct in rules 1.56(b)(2) and 1.555(b)(2) are different than the persons required to submit information under rules 1.56(a) and 1.555(a). Under the proposed new rule, only misconduct by the applicant or the patent owner would be considered to determine whether the information was material while rules 1.56(a) and 1.555(a) apply to “Each individual associated with the filing and prosecution of a patent application” or “Each individual associated with the patent owner in a reexamination proceeding.” It would seem that affirmative egregious misconduct would be relevant in the examination or reexamination of a patent application whether it was committed by the patent owner or applicant or by anyone associated with the patent owner or applicant, for example, the attorney or agent.

Also relevant to this issue, one comment that we received suggested modifying rule 1.56(d) to indicate that, if an inventor is represented by an attorney or agent, then the submission of information by the inventor to the attorney or agent is sufficient to satisfy the duty of disclosure for inventor. Currently, rule 1.56(d) does not exempt the inventor from the duty of disclosure even if the inventor provides the information to counsel.

Thus, AIPLA suggests that the “affirmative egregious misconduct” referred to in the *Therasense* decision either should be moved to 37 C.F.R. §§1.56(a) and 1.555(a) or moved to separate rules that parallel rules 1.56 and 1.555, and that the rules state in a more consistent way to whom they apply.

Second, we are concerned with the statement in the new rule that information is material to patentability if “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.” In particular, we believe that the phrase “broadest reasonable construction” is incomplete. The phrase should be “broadest reasonable construction as it would be understood by a person of ordinary skill in view of the specification.” This standard is required for claim analysis by *In re Suitco Surface Inc.*² In *Suitco*, the Federal Circuit invoked the specification and the skilled person to prevent an overly broad construction by the Office. Without this language in the rule, applicants may believe that they need to use an overly broad claim construction to determine what information must be cited to the Office. This may add uncertainty to the process and result in the submission of art that is not only immaterial but irrelevant.

A third concern that has been expressed by many of our members is that the “but for plus” test may result in the withholding of references that are not material under the test but may be helpful to the examiner in understanding the invention. In particular, our some of our members believe that the submission of a reference may be interpreted as an admission that it meets the “but-for” test.

² 603 F.3d 1255, 1260 (Fed. Cir. 2010) (“Although the PTO emphasizes that it was required to give all ‘claims their broadest reasonable construction’ particularly with respect to claim 4’s use of the open-ended term ‘comprising,’ ... this court has instructed that any such construction be ‘consistent with the specification, ... and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.’”) (citations omitted, emphasis in original).

While rule §1.97(h) states that “The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b),” this statement may not be sufficient to encourage applicants to submit references that may be helpful to the examiner even though they are not material. Thus we recommend adding a statement to rule 1.97 encouraging the submission of information that may not be material but that the applicant believes would be helpful to the examiner. If the Office does not make this modification to the rule, it would be helpful to add such a statement to the commentary accompanying the final rule.

Fourth, we are concerned by the explicit citation of the *Therasense* case in the rules. Cases are often interpreted in later decisions and the law that is applied may be modified by these interpretations. The specific reference may lock the Office into the standard as it is applied in that decision and result in diverging standards between the courts and the Office.

Fifth, we recommend amending the draft rules 1.56(b) and 1.555(b) to reinstate the statement that “information is material to patentability when it is not cumulative to information already of record or being made of record in the application.” While we understand cumulative information would not be a “but-for” reference, we believe that some may interpret the omission of this statement as requiring the submission of a particularly material reference even though it is cumulative.

AIPLA also has concerns with the commentary in the Federal Register Notice. In particular, the notice indicates that the Office is considering further actions that may provide an incentive for applicants to assist the office by explaining/clarifying the relationship of prior art to the claimed invention. In this regard, however, we recommend that the Office issue guidelines which state that any such explanatory disclosure, or disclosures, or the omission of other explanatory disclosures, would not be considered to be an affirmative act of egregious misconduct if there is any reasonable basis for the explanatory disclosure or its omission. Also, any such guidelines should indicate that an applicant’s identification of a specific portion of a reference is only an indication that the applicant has knowledge that the identified portion may be of interest, and was the reason the reference was cited. Furthermore it should be understood that there may be one or more other portions in the reference that might be as relevant, or even more relevant.

In a similar vein, we recommend that the Office provide one or more safe-harbor provisions into the rule to clarify that certain types of material are cumulative or unnecessary for applicants to provide (or in many case, re-provide) to the Office. In particular, materials from other related cases pending in the Office should not have to be provided in every other related case that is pending. This form of cross-citation often comprises the bulk of all submissions to the Office by applicants, and was in large part engendered by the holding in the *McKesson Information Solutions, Inc. v. Bridge Med., Inc.*³ It would be a significant benefit to both the Office and to applicants if the Office would (a) provide a standard method for cross-citation of related cases, and (b) clarify that, once cross-cited, materials cited or office actions and responses in related cases need not be cited or provided in any other related case. The Office should be deemed to have checked whether other citations were made in related pending cases, and to have determined whether they are relevant to the case at hand.

³ 487 F.3d 897 (Fed. Cir. 2007)

There are likely other areas where the Office can properly provide safe harbor provisions that clarify and simplify the citation process, and we encourage the Office to provide such additional guidance.

Finally, either in the rule itself or in the guidelines, the Office should indicate that any application of the “but-for plus” test as to the materiality of information or of alleged affirmative egregious misconduct should take into account rebuttal evidence or arguments presented by the applicant. The “but for plus” test should not be interpreted as a per se rule.

In conclusion, while we agree with the goal of the Office to make the duty of disclosure under rules 1.56 and 1.555 consistent with the standards used for inequitable conduct in courts, we believe that some work still needs to be done on these rules to tailor them to patent prosecution and reexamination practice.

Thank you for your kind consideration,

Sincerely,

A handwritten signature in black ink that reads "David W. Hill". The signature is written in a cursive, flowing style.

David Hill
AIPLA President