From: Winkler, Michael [e-mail address redacted] Sent: Wednesday, September 28, 2011 3:11 PM

To: AC58. comments

Subject: Comments from ABA Section of Intellectual Property Law on proposed

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Please find attached comments from the ABA Section of Intellectual Property Law on Proposed Changes to 37 C.F.R. $\S1.56$ and $\S1.555(b)$ at 76 Federal Register 140 (July 21, 2011). We realized these comments are being submitted past the stated deadline in the Federal Register. We submit them in any event, for the record, and hope they will be useful to you.

Please feel free to contact us if there are any questions.

Thank you.

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September 27, 2011

Via electronic mail

AC58.comments@uspto.gov

The Honorable David 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

Attn: Hiram H. Bernstein, Senior Legal Advisor, Office of

Patent Legal Administration, Office of the Associate

Commissioner for Patent Examination Policy

Re: Comments on Proposed Changes to 37 C.F.R. §1.56 and

§1.555(b) at 76 Federal Register 140 (July 21, 2011)

Dear Under Secretary Kappos:

I am pleased on behalf of the Section of Intellectual Property Law of the American Bar Association to offer technical comments on the proposed rulemaking relating, *inter alia*, to the provisions of 37 C.F.R. §1.56. The resolution and report of the Section relating to these comments are attached at the end of this letter. These comments have not been approved by the American Bar Association's House of Delegates or Board of Governors and should not be considered to be views of the American Bar Association.

The Section believes that the explicit reference in existing Rule 56 to "cumulative" information as not being material to patentability should be retained in any future rulemaking effort, even in the event the Office proceeds to adopt the *Therasense* holding itself as the standard for the duty of disclosure imposed upon patent applicants. We believe such an explicit reference is essential to completely foreclose any argument in a patent enforcement context that the Office's omission of the explicit reference to "cumulative" information might suggest that in some circumstances under *Therasense* that such merely cumulative information might require disclosure during the patent examination process.

The Section is continuing its analysis of the proposed rules and intends to address other aspects of the rulemaking proposal in November. Thus, please consider the comments in this communication to be preliminary in nature, pending that fuller consideration of the issue later in the year. We realize that the period for comment on the proposed rules as set out in the notice of proposed rulemaking has expired. Nonetheless, we would appreciate any consideration that might be given to these comments, as well as any further comments that may result from our further deliberations.

Rulemaking on this subject is of critical importance to both the Office and individuals appearing before the Office, particularly given the infrequency with which revisions to Rule 56 can be expected. Thus, we applaud the efforts by the Office to modernize the rule and hope that the promulgation of any final rules on this subject will result in improved quality and efficiency in the patent examination process.

If you have any questions regarding our comments or would wish for us to explain further any of our comments, please feel free to contact me. Either I or another member of the leadership of the Section will respond to any inquiry.

Very truly yours,

Robert A. Armitage

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Section Chair

American Bar Association

Section of Intellectual Property Law

ABA-IPL SECTION RESOLUTION

RESOLVED, that the Section of Intellectual Property Law favors, in principle, in any regulations purporting to clarify, modify, or restate that standard for "materiality" in connection with the "duty of candor and good faith" under 37 C.F.R. §1.56, that such regulations continue to provide in an explicit manner that information that would be merely cumulative with respect to information already provided to the Office in connection with a particular matter or proceeding is not material with to respect the issues before the Office in that matter or proceeding; and

NOW THEREFORE, the Section supports in the specific text appearing in amended 37 C.F.R §1.56(b) and 37 C.F.R. § 1.555(b) in 76 Fed. Reg. 149 (July 21, 2011) an explicit statement addressing materiality with respect to information that is merely cumulative.

DISCUSSION

The PTO proposes to replace paragraph (b) in both 37 CFR § 1.56 and 37 CFR § 1.555 with language reflecting the materiality standard set forth in the *Therasense* decision. In doing so, the PTO would remove language relating to cumulative information. These comments have not been approved by the American Bar Association's House of Delegates or Board of Governors and should not be considered to be views of the American Bar Association.

Specifically, under the PTO's proposal, the following language would no longer appear in either rule:

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

The Section questions why the PTO proposes to remove this language. During a Q&A session at the 2011 ABA Annual Meeting in Toronto, certain PTO personnel suggested that the "but for" materiality standard of *Therasense* would subsume the "cumulative information" language that would be removed from the rule. In other words, if certain information were cumulative to what was already in the record, then the absence of that information would not affect the PTO's patentability determination, and under *Therasense* the information would not be material.

The Section nonetheless believes that the inclusion of this or like language is important. First, there may be those who disagree with the position that the "but for" materiality test would exclude all cumulative information. This could lead to confusion among practitioners as to whether cumulative information need be submitted or not. Second, litigants may seek to capitalize on the absence of the cumulative information language, arguing that a patent owner committed inequitable conduct by failing to submit cumulative

art. If nothing else, the patent owner may need to go through the additional effort of explaining to a patent-inexperienced judge why cumulative information falls outside the new materiality standard. Such a step is not necessary under the current rules, in which cumulative information is explicitly excluded from the definition of materiality.

The Section recognizes that there may be some benefit to reciting the *Therasense* standard alone; namely, simplicity. In this case, however, the disadvantages described above outweigh any potential benefit. For this reason, the Section recommends that the PTO maintain the cumulative information language within the Duty of Disclosure rules. One way of doing this would be to incorporate the language from the existing rules into the PTO's revised rules:

- (b) . . . Information is material to patentability under *Therasense* <u>if it is</u> <u>not cumulative to information already of record or being made of record in the application and if:</u>
- (1) The Office would not allow a claim if it were aware of the information

Proposed Revision to § 1.56, 76 Fed. Reg. 43634 (with emphasis to show suggested incorporation). Other suitable revisions would achieve the same end.