COMMENTS TO THE USPTO
ON *THERASENSE* PROPOSED RULES

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INTRODUCTION

The National Association of Patent Practitioners (NAPP) is a nonprofit trade association for patent agents and patent attorneys. NAPP has approximately 400 members in the US and various foreign countries. The practices of the practitioner members are focused primarily on patent prosecution, namely practice before the USPTO. As part of NAPP's mission, we aim to create a collective nationwide voice to address issues relating to patent-prosecution practice. Additional information about NAPP can be found at www.napp.org.

The following comments are submitted in an effort to assist the United States Patent & Trademark Office (USPTO) in response to request for comments, "Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications," published in the Federal Register at 76 Fed. Reg. 43631 (July 21, 2011).

NAPP welcomes the opportunity to assist and hopes that the USPTO will seriously consider the comments of NAPP. NAPP would be happy to help USPTO and is available to answer questions, comment further (formally or informally), or assist any other way considered useful.

NAPP COMMENTS

Comment #1. **The proposed amendments to Rules 56 and 555 are generally worthwhile.** In general, NAPP applauds the stated goals of the proposed rules and supports the proposed revision of Rules 56 and 555, amending the "materiality" standard to align with *Therasense, Inc. v. Becton, Dickinson & Co.* (Fed. Cir. 2011) (en banc). Those of us who prepare and prosecute patent applications should be held to the same standard as would apply in litigation of issued patents.

The courts no longer require that every conceivable reference be cited to the Office to forestall a charge of inequitable conduct. They recognize that past standards have, perversely, resulted in a flood of references being submitted, thereby necessarily obscuring discussion of close references and requiring examiners to spend time reviewing more remote ones. The *Therasense* standard allows – indeed, encourages – a much shorter and more meaningful list of citations. This enhances patent quality and benefits everyone. Absent change to Rule 56, however, patent prosecutors will consider their ethical duties as requiring them to follow the old system, and the great opportunity provided by *Therasense* will go unused.

Comment #2. **Rules 56 and 555 should not explicitly refer to the *Therasense* case.** Reference to *Therasense* itself should be omitted from Rules 56 and 555. In part (b) of Rule 56, for example, the preamble says: "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) … or (2) …."

This way of phrasing the issue presents a number of problems:

a) It can lead to ambiguity. What if a practitioner, or a court, or the Office were some day to conclude that, as applied to some specific circumstance, the "(1) or (2)" standard as written does not match exactly the standard set forth in *Therasense*? Should *Therasense* apply or the "(1) or (2)" standard?

b) Practitioners ought to be able to review the rule itself and understand it on its face, without need to locate, study, and interpret the *Therasense* case.

c) Over time, such phrasing is likely to result in a growing gap between court decisions and the rule, precisely the opposite of what the PTO apparently desires. Consider, for example, what happens when the Federal Circuit (or the Supreme Court) issues the next important decision on the subject of inequitable conduct. If Rule 56 explicitly incorporates the standard as set forth in *Therasense*, does that mean that Rule 56 ought to be interpreted to ignore all refinement to inequitable-conduct standards that might be explained in such a later case?

In sum, the two-part "(1) or (2)" standard is clear, and it is sufficient by itself. The reference to *Therasense* ought to be removed from the preamble of the rule, leaving just the "(1) or (2)" standard. Reference to *Therasense* in the regulatory record is fine, but it should be omitted from the rule itself.

Comment #3. The new rules should include a "safe harbor" to address *McKesson*. Modification to Rule 56 presents a significant and rare opportunity to address issues of practical concern to practitioners. For example, in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.,* 487 F.3d 897 (Fed. Cir. 2007), a patent applicant was faulted for not having cited, in one application, references that he had cited in a different application in the same patent family (both claiming priority to the same ancestor application). He was further faulted for

not having cited references that had been cited in a related, but separate, family. The same could apply to PTO-issued office actions in related cases.

In reaction to *McKesson*, practitioners began citing large quantities of information from related cases, all of which are available to the examiners easily (provided the related application is identified), including duplicates of references and copies of office actions. Such practices have contributed to the size of Information Disclosure Statements and burdened examiners, not to mention imposing extra cost on applicants and creating added risk to practitioners arising from mistakes in cross-citing, all in exchange for no corresponding benefit to examiners.

Under the standard in *Therasense*, such practices should have no place. However, it is not clear that practitioners will universally understand the proposed rule to allow for relaxation of citations in this category.

Accordingly, NAPP suggests addition of an explicit "safe harbor" to allow practitioners to refer to references and material in related applications in an easy and concise fashion. For example, Rules 56(a) and 555(a) (or Rule 97) should be amended to add language that would relieve applicants from filing lists of references cited in other cases in favor of allowing them simply to identify the application in which they can be found and suggest that the examiner might wish to review such files. Language such as the following might be appropriate:

> An information disclosure statement may cite a related patent application by listing an application serial number and filing date and describing the nature of the relationship (*e.g.*, parent, child, sibling, or commonly owned), and the Office shall consider such a citation as referring to all references and information of record in the cited application.

Comment #4. **Rule 56 should be amended to terminate the duty of disclosure at the time the issue fee is paid.** Rule 56(a) currently terminates the duty of disclosure only after the claim to which information pertains has been canceled (or, in the case of Rule 56(a), when the entire application has been abandoned), or until the patent issue date. The duty of disclosure remains even when prosecution on the merits has been closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935), even when a notice of allowance has issued, and even when the issue fee has been paid. *See*, *e.g.*, MPEP 2001.04 ("The duty to disclose information, however, does not end when an application becomes allowed but extends until a patent is granted"); MPEP 2004 ("That the issue fee has been paid is no reason or excuse for failing to submit information").

Conversely, the holder of an issued patent has no duty (upon later discovering prior art) to apply for reexamination or reissue. He may well do so before suing. However, it is proper for him to maintain a patent even though he knows of later-discovered prior art.

If an applicant discovers new prior art references or information between the close of prosecution (*Quayle* or allowance) and the date of issuance, there are procedures to address the matter. Before payment of an issue fee, an applicant can cite recently discovered art, and the examiner is duty bound to consider it. *See* Rule 97(c); MPEP 609.04(b)(III).

After payment of an issue fee, however, applicants may not file an Information Disclosure Statement. *See* Rule 97(d), (e). The Office admits, "After the issue fee has been paid on an application, it is impractical for the Office to attempt to consider newly submitted information. Information disclosure statements filed

after payment of the issue fee in an application will not be considered but will merely be placed in the application file." MPEP 609.04(b)(IV).

Applicants' only remedies during that period are to reopen prosecution by withdrawing the patent from issue (with a petition that must state claims are unpatentable) or filing a request for continued examination, which has the effect of preventing issuance and delaying matters. *See* MPEP 609.04(b)(IV) and 37 C.F.R. §1.313(c)(1).

These circumstances put applicants in an awkward position in instances when they learn of a close reference that might or might not be considered patent-defeating, and might or might not meet the standard in Rule 56(b)(1) as the Office currently proposes to amend it. Should applicants in this position file an RCE (or a continuation) to address that reference, petition to withdraw, or allow the claims to issue and perhaps file a continuation? These are difficult questions. Such issues are not fixed by the proposed amendments, but they *should* be fixed.

NAPP respectfully submits that Rule 56 should be amended further to clarify that the duty of disclosure ends at the time of payment of the issue fee, not at issuance.

If it is impractical for the PTO to consider citations during that period, practitioners should not be required to cite them. The PTO rules absolve the PTO from *considering* references during this awkward period, and they should likewise absolve applicants and practitioners from *citing* them.

Any references first uncovered after payment of an issue fee can be handled just as they are now, and just as they are handled after issuance, namely simply placing the citation in the application file. *See* 37 C.F.R. §1.501. (Also, the new statute allowing for post-grant opposition could relieve any problems in some cases.)

Such a change could be implemented by amending Rule 56(a) as follows: "The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned, or until the issue fee is paid, in the event the application is allowed." Or, a "safe harbor" can be put elsewhere in Rule 56 or in Rule 97.

Comment #5. Rules 56 and 555 should not drop the phrase "consistent with the specification". Rules 56(b) and 555(b), as they now stand, recite hornbook law that claims are to be construed "giving each term in the claim its broadest reasonable construction *consistent with the specification*." [Emphasis added] As proposed, the amended rule drops the phrase "consistent with the specification." *Compare* current Rule 56(b) ("…giving each term in the claim its broadest reasonable construction consistent with the specification") *with* proposed Rule 56(b)(1) ("… and giving the claim its broadest reasonable construction").

NAPP assumes that this omission was an oversight or simple rewording choice and that no change in the law, or Office procedure, was intended.

If such a change was intended, then the Office should give examples of how typical claims would be examined differently under the old rules and the new rules. If no such change was intended, then the omitted phrase ("consistent with the specification") should be restored.

Conclusion

NAPP thanks the PTO for the opportunity to comment and offers to provide whatever further assistance is needed in relation to these important amendments.