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September 26, 2011

Hon. David J. Kappos
Director
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313
Attention: Hiram H. Bernstein

Submitted via e-mail to AC58.comments@uspto.gov

Dear Director Kappos:

We appreciate the opportunity to provide comments on the notice of proposed rulemaking titled “Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications,” published at 76 Fed. Reg. 43631 on July 21, 2011.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO’s membership includes more than 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members.

Introduction

We support in principle the proposed changes in 37 CFR §§1.56 and 1.555, which would incorporate into the rules the standard for materiality adopted by the Federal Circuit in *Therasense, Inc. v. Becton, Dickinson & Co.*, ___ F.3d ___, 2011 WL 2028255 (Fed. Cir. 2011) (*en banc*). Subject to recommendations below, we support incorporation of the *Therasense* standard into the rules, because it is the standard now used by the Federal Circuit for inequitable conduct and it is simplest for applicants for the PTO’s standard for duty of disclosure to match the Federal Circuit’s standard for inequitable conduct.

Therasense “But-For-Plus” Standard

In July 2010, IPO filed an *amicus* brief in the *Therasense* case in which IPO argued that the materiality bar for inequitable conduct needed to be raised to an objective “but for” standard. The “reasonable examiner” standard that had its origins in the 1977 version of §1.56 and the amended §1.56, adopted in 1992, had unintended consequences. Those rules as applied by the courts to determine inequitable conduct led to the “cite everything, say nothing” practice that has caused examiners to be frequently overwhelmed with irrelevant references, making the most relevant prior art more difficult to identify. In its brief, IPO urged the court to overrule its prior panel decisions,

which it did, establishing a single standard for inequitable conduct. The “but for” standard aligns closely with the “unclean hands” underpinnings of inequitable conduct as stated in the Supreme Court’s *Precision Instruments* and *Keystone Driller* cases. An objective but for standard is the proper standard because patent unenforceability is a drastic remedy and materiality should not be considered in terms of whether information possibly may have affected an examiner’s analysis. Rather, the measure of materiality should be substantial and based on more than mere possibility when it is used to bar enforcement of an issued patent.

IPO did not advocate for or anticipate the “plus” portion of the materiality standard adopted by the court, which is described as “affirmative egregious misconduct.” As noted in the *Federal Register* notice, the court said neither mere nondisclosure of information to the Office nor failure to mention information in an affidavit, declaration, or other statement to the Office constitutes affirmative egregious misconduct. ___ F.3d at ___, 2011 WL 2028255, at *12. We hope the concept of affirmative egregious misconduct will be defined more clearly in future court opinions, but it is part of the *Therasense* materiality standard.

Tensions in a Disclosure Standard Based on the *Therasense* Standard

The *Federal Register* notice states, “The Office recognizes the tension inherent in a disclosure standard based on unpatentability” We agree tension exists. Proposed §1.56(b) and the parallel rule for reexamination, proposed §1.555(b), state that information is material to patentability under *Therasense* 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 interpretation.” This is the language the court used to define the but for standard. If a world existed where the meaning of patent claims and the meaning of the prior art were always crystal clear, the *Therasense* standard would never require ANY disclosure of information to the Office, assuming applicants avoided drafting claims that were unpatentable in the face of the prior art they knew about. In the real world, however, language usually cannot make claims and the prior art perfectly clear.

We believe the Office’s proposal for a disclosure duty based on unpatentability would cause applicants to cite prior art within a penumbra around the standard. Applicants likely would cite less prior art, however, than under the “reasonable examiner” and other standards followed by the Federal Circuit before *Therasense*. We note with approval the statement in the *Federal Register* that “the Office will not regard information disclosures as admissions of unpatentability for any claims in the application.”

Tension also exists in the passage, “applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction,” which is taken from *Therasense*. This passage causes the materiality standard to differ from the standard for holding a patent claim invalid in court. In its *Therasense* brief, IPO argued that the objective but for standard would promote beneficial bifurcation of inequitable conduct

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issues, which most commonly would be tried only after the judge or jury found a claim of an asserted patent to be invalid. With the requirement to apply the but for standard with the preponderance of the evidence standard and broadest reasonable claim construction, bifurcation of invalidity and inequitable conduct may be less likely. We hope future case law developments can relieve the tension.

Recommendations

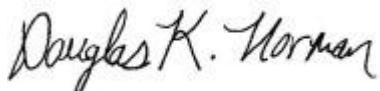
In order to make the materiality standard easier to understand, add an introductory sentence to proposed §1.56(b) along the lines of the following: “While the Office encourages applicants to examine the closest information (see paragraph (a) of this section), the duty to disclose information applies only to information material to patentability as defined in this section.”

The language of proposed §1.56(b) captures the *Therasense* but-for-plus materiality standard accurately. It is unnecessary to include the name and citation of the *Therasense* case in the rule. Future cases may elaborate on the meaning of the words used in *Therasense*, and updating may be easier without case names in the rule.

The Office should take the opportunity to amend the rules to eliminate the need to cite and submit co-pending applications, office actions and responses in those co-pending applications, and other, similar information in the Office’s possession.

Thank you for responding to the *Therasense* decision so quickly. We stand ready to assist the Office in any way we can.

Sincerely,



Douglas K. Norman
President