



22 December 2016

The Honorable Drew Hirschfeld
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Attention: Matthew Sked, Legal Advisor, Office of Patent Legal Administration

Via email: AC58.comments@uspto.gov

Re: IPO’s Comments on the Duty to Disclose Information in Patent Applications and Reexamination Proceedings

Dear Commissioner Hirschfeld:

Intellectual Property Owners Association (IPO) submits the following comments on the notice of proposed rulemaking titled “Revision of the Duty to Disclose Information in Patent Applications and Reexamination Proceedings,” published at 81 Fed. Reg. 74987 (Oct. 28, 2016) (FRN).

IPO is an international 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 about 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. IPO membership spans more than 50 countries. IPO advocates for effective and affordable IP ownership rights and provides a wide array of services to members, including supporting member interests relating to legislative and international issues; analyzing current intellectual property issues; information and educational services; and disseminating information to the general public on the importance of IP rights.

Introduction

Subject to recommendations below, and because it is simplest for applicants to have the USPTO’s duty of disclosure standard match the Federal Circuit’s standard for inequitable conduct, we support incorporating into 37 C.F.R. §§1.56 and 1.555 the standard for materiality adopted by the Federal Circuit in Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

Therasense “But-For-Plus” Standard

In July 2010 IPO filed an amicus brief in Therasense arguing that the materiality standard for inequitable conduct should 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

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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 our 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* opinions. See *Precision Instrument Mfg. Co. v. Automotive Co.*, 324 U.S. 806 (1945); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).

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 *might* have affected an examiner’s analysis. 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 standard adopted by the court, which is described as “affirmative egregious misconduct.” As noted in the FRN, the court in *Therasense* said neither mere nondisclosure of prior art to the USPTO nor failure to mention prior art in an affidavit, declaration, or other statement to the USPTO constitutes affirmative egregious misconduct. 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 FRN states that “the Office recognizes the tension inherent in a disclosure standard based on unpatentability.” We agree. Proposed § 1.56(b) and the parallel rule for reexamination, proposed § 1.555(b), state that information is but-for material to patentability if “the Office would not find a claim patentable if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.” 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 disclosure of information to the USPTO, 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.

The USPTO’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 FRN that the USPTO will not regard information disclosures as admissions of unpatentability for any claims in the application. See 81 Fed. Reg. 74987, 74994 cmt. 22-23 and responses (Oct. 28, 2016).

Tension also exists in the passage “applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification,” which is partly taken from *Therasense*. This passage causes the materiality standard to differ from the standard for holding a patent claim invalid in court. In our *Therasense* amicus brief, IPO

explained that the objective but-for standard would promote beneficial bifurcation of inequitable conduct 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 consistent with the specification, bifurcation of invalidity and inequitable conduct might be less likely. We hope future case law developments can relieve the tension.

Satisfaction of Applicant’s Duty of Disclosure with Respect to Information Received from “Monitored” Applications

The comments in this section are consistent with our 28 October 2016 comments to the USPTO on “Leveraging Electronic Resources to Retrieve Information From Applicant’s Other Applications and Streamline Patent Issuance.” If the USPTO implements a program to monitor other applications when examining a given application, Proposed § 1.56 should be modified so that an applicant’s duty of disclosure is satisfied with respect to all information imported from applications monitored.

We recommend importing information from monitored applications into the file wrapper of a given application via the Global Dossier tool to ensure the information is considered and of record in the given application, making any submission of this information by applicant cumulative and unnecessary to satisfy an applicant’s duty to disclose under § 1.56. By receiving information from monitored applications in this manner, an examiner should be able to determine the relevance of the imported information much quicker than if that same information was merely cited by the applicant in an IDS. The information might be able to be considered by an examiner more effectively and meaningfully while simultaneously relieving the applicant of the duty to disclose it.

Monitored applications might include, for example, applications that share a priority relationship with a given application such as a parent, child, sibling, or foreign counterpart; other co-pending domestic or foreign applications that do not share a priority relationship but that are directed to related subject matter; and applications of another applicant in the same technology space as a given application.

We expect that at this time monitored applications would include only applications pending in IP5 offices, because the USPTO can automatically import all relevant information from IP5 applications into the record of applications pending before the USPTO through the Global Dossier tool. We recommend that the USPTO continue to expand the Global Dossier tool to include information from other patent offices and to make information about monitored applications available to the USPTO pre-publication to ensure information from monitored unpublished applications is available to the USPTO as soon as possible during examination. Until the Global Dossier tool is expanded, applicants should continue to cite material information not available through the Global Dossier tool using IDSs.

Recommendations

To make the materiality standard easier to understand, we suggest adding an introductory sentence to Proposed § 1.56(b) along the lines of the following: “Although the Office

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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.”

We support not including the name and citation for *Therasense* in § 1.56(b) because Proposed § 1.56(b) captures its but-for-plus materiality standard accurately. Making updates based on future case law elaborating on *Therasense* will 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 USPTO’s possession.

As noted above, IPO suggests that an applicant’s duty of disclosure be satisfied with respect to all information imported from applications monitored through its new program. If an application is monitored, the duty of disclosure should be deemed satisfied for all information in that application without further action by applicant because that information is in the record of a given application, rendering further submission in an IDS by an applicant cumulative. The USPTO could clarify this in various ways, for example by modifying § 1.56 to state that information received in a given application from monitored applications is deemed cumulative of information already of record or adding a section noting that the duty of disclosure does not extend to information received in a given application from applications being monitored through its program. The USPTO could also modify the MPEP to expressly state that it is not necessary for applicants to submit an IDS with information received in a given application from monitored applications (similar to the handling of information from parent applications under MPEP § 609.02).

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

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Lauroesch", written in a cursive style.

Mark Lauroesch
Executive Director