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Via E-mail to [AC58.comments@uspto.gov](mailto:AC58.comments@uspto.gov)

c/o Hiram H. Bernstein, Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner for Patent Examination Policy

Dear Mr. Bernstein:

I am writing to comment on the proposal by the Patent and Trademark Office (the “Office”) to revise the materiality standard set forth in 37 C.F.R. 1.56(b) (and 1.555(b)) for consistency with *Therasense, Inc. v. Becton, Dickinson & Co.*, \_\_\_ F.3d \_\_\_, 2011 WL 2028255 (Fed. Cir. 2011) (en banc). 76 Fed. Red. 43632-43634. The following table of contents indicates the broad topics that I will discuss below.

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**General Agreement with the Office’s Proposals**

I generally agree with the Office’s proposal to revise Rules 1.56 and 1.555 for consistency with *Therasense*. I also note that the “but-for-plus” standard proposed by the

Office now is almost identical to the “but-for” standard that the Office originally proposed in March of 1989. 54 Fed. Reg. 11334.

**The Office Should Preserve the Language “Consistent with the Specification” in Rules 1.56(b) and 1.555(b)**

Current Rules 1.56(b) and 1.555(b) quote the standard for claim construction as the “broadest reasonable construction consistent with the specification.” For reasons that are mysterious, the Office recommends eliminating the phrase “consistent with the specification” in proposed Rules 1.56(b) and 1.555(b).

Although the omission may have been innocent, the Office should restore the original, fuller, and more accurate language “broadest reasonable construction consistent with the specification.” In my experience, examiners routinely abuse the “broadest reasonable interpretation” rubric by interpreting claim language in a manner **inconsistent** with the specification. Indeed, until appeal, examiners all too often view the “broadest reasonable interpretation” rubric as a license to interpret claims as broadly as they like, in an attempt to force applicants to make unnecessary claim amendments. For that reason alone, the language “consistent with the specification” should be preserved in Rules 1.56 and 1.555 and throughout Office regulations as appropriate.

**The Office Should Not Require the Redundant Submission of Information in Applications that the Office Knows to be Related**

The Office currently requires applicants to redundantly submit information that was previously submitted in related applications. The requirement exists even when the applicant has already identified the relatedness between applications (e.g. by claiming the benefit of a parent application in a continuation). MPEP 2004 (“It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material.”).

The requirement to redundantly submit information is unwise on its face for many reasons. First, it needlessly requires redundant work and additional paperwork instead of requiring the examiner to use information already in his or her possession. Secondly, it places the burden on persons associated with the application, who face catastrophic risks in the case of alleged non-compliance, instead of the examiner, who faces comparatively little or no risk when failing to consider the information. The burden should be allocated to avoid asymmetric risk of catastrophic harm.

In view of the above, the Office should provide a simple mechanism for designating that applications are related such that information submitted in one application should be considered in the other. Applicants may do this, for example, by making such a statement in an application data sheet or information disclosure statement.

**Office Regulations Should Relax Burdens On Submitting Information When There is No Duty to Submit the Information**

Although Rules 1.56 and 1.555 define what persons under a duty must disclose to the Office, these persons are free to disclose other information. For example, a person

submitting information may merely have a reason to suspect that information is material, without knowing that the information is, in fact, material, as required by Rule 1.56. Indeed, it is common for applicants and practitioners to learn of a foreign search report indicating that information may be material, without reviewing either the cited references or foreign office action (if the foreign patent office issues a rejection). Many such search reports and references are not even in the English language.

In other cases, persons may submit information whenever the information raises the slightest question of materiality, even if they feel resolute that the information is, in fact, not material, simply to hedge their bets. Indeed, the Office explicitly encourages persons to submit information in these cases, even though they are under no duty to do so. MPEP 2004 (“In short, the question of relevancy in close cases, should be left to the examiner and not the applicant.” (internal citation omitted)).

Although the majority of information is volunteered to the Office in these manners, without a genuine duty to submit the information, Office regulations place a large burden on applicants to submit information after a first office action, regardless of whether the duty exists. Specifically, Rule 1.97 places increasing burdens on applicants to submit information after the first action but before prosecution is closed (Rule 1.97(c)), after prosecution is closed and before payment of the issue fee (Rule 1.97(d)), and after payment of the issue fee but before issuance (MPEP 1308).

In part because the Office places these burdens on the submission of information, even when no duty exists to submit it, practitioners sometimes resort to desperate tactics to balance the benefits and costs of disclosure. For example, some practitioners will submit information under Rule 1.97(i), which states “If an information disclosure statement does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office.” Rule 1.97(i) merely explains what happens when information is improperly submitted to the Office. It does not provide a mechanism for the submission of information when no duty of disclosure exists, much less condone the use of Rule 1.97(i) to submit information in those situations. Nevertheless, the onerous burdens that the Office places on persons to submit information, even when no duty exists to submit it, results in those persons resorting to such desperate tactics.

When applicants and other person associated with an application go **above and beyond** the duty of disclosure to submit information to the Office, simply to aid the Office in its examination, without having a duty to disclose the information, the Office should not punish them with extra burdens for submission. In most cases, examiners will not use the information and, in many cases, they will even ignore it. The Office should encourage the submission of such information, when no duty exists, by permitting persons to submit the information liberally at no cost.

In view of the above, Office regulations should distinguish between the submission of information when a duty exists and when a duty does not exist to submit the information. When a duty does not exist, the Office should relax or eliminate any

burdens on submitting the information. For example, the Office could revise Rule 1.97(i) by adding a subsection as follows, while revising the remainder of Rule 1.97 for consistency (i.e. by distinguishing between when information is submitted freely or under an existing duty to disclose):

(i) At any time, information may be submitted to the office by a person at no cost when the person is under no duty to disclose the information. When disclosing the information, the person must certify that he or she does not know that the information is material, or believes it to be immaterial, and must provide a brief explanation for the certification.

~~(j)~~(j) If an information disclosure statement does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office.

The proposed revision here would not overburden the Office for the simple reason that, because the applicant does not know the information to be material, there should not be an inflexible requirement for the examiner to consider it. Rather, the examiner should consider the information according to the time and resource limitations imposed upon the examiner as appropriate. Further, if the examiner does use the information in a later office action after the issuance of a first action, then Office guidance compensates the examiner, and Office, by permitting the examiner to make the later action final. MPEP 706.07(a).

### **The Office Should Define the Duty of Disclosure as Ending upon Payment of the Issue Fee**

One of the greatest burdens imposed by current Rules 1.56 and 1.555 is that the duty of disclosure has been held to continue after payment of the issue fee until the patent issues. 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.”) (citing *Elmwood Liquid Products, Inc. v. Singleton Packing Corp.*, 328 F. Supp. 974, 170 USPQ 398 (M.D. Fla. 1971)). The problem is that the burden to submit information after payment of the issue fee is tremendous, and dramatically higher than to do so before payment. Specifically, applicants are required to restart the entire examination procedure by filing a petition certifying that the claims are unpatentable or by filing a request for continued examination. MPEP 1308 and 2001.03.

The burden to submit information after payment of the issue fee is especially acute when persons discover information that may be material without a duty existing to submit the information, as discussed above. In many case, applicants spend thousands of dollars to reopen prosecution simply because a foreign patent office listed a reference in a search report, even though the information is not material and/or was not known to be material under either current or proposed Rules 1.56 and 1.555, and even though the examiner, upon receiving the information, merely marks the information as considered before issuing a redundant notice of allowance. In these and other cases, it would simply be better for the applicant to be under to no duty to submit information at that time. The

revision here would be complimented by the mechanism, proposed above, to allow a person to submit information at any time, and at no cost, that the person certifies is not known to be material.

### **The Office Is Not Required to Mimic the Federal Circuit**

Although I believe that the Office is wise to follow the Federal Circuit in this situation, it is important to remember that the Office is not bound by the Federal Circuit's holding in *Therasense* when promulgating or revising Rules 1.56 and 1.555. When the en banc decision in *Therasense* was first issued, at least one eminent patent scholar warned that a failure of the Office to make Rules 1.56 and 1.555 consistent with *Therasense* would result in dire consequences. Upon scrutiny, however, the only dire consequence appears to have been the possibility of legal uncertainty during the period of potential review by the Supreme Court. Since the time has already lapsed for filing a petition for certiorari in *Therasense*, and no petition was filed, this single concern is obviated and no other concerns remain.

In view of the above, there is *no* apparent reason for the Office to feel compelled to make Rules 1.56 and 1.555 consistent with *Therasense*. It is not clear what has motivated the Office to abandon its earlier position, which it argued in *Therasense*, that the materiality standard in current Rules 1.56 and 1.555 is superior to the fraud-based standard adopted by the Federal Circuit (i.e. because a fraud-based standard would result in under-disclosure). Although the Federal Circuit rejected the Office's position, the holding in *Therasense* does not control how the Office must define its own Rules when regulating conduct before the Office.

There are important reasons to think that dual standards for a duty to disclose (between the Office and the court) are both possible and desirable. Dual standards would be possible in the same way that dual standards for other legal doctrines differ between the Office and courts. For example, the Office and courts apply significantly different standards for, *inter alia*: general claim construction, construction of product-by-process claims, evidence, and the presumption of validity. Although these dual standards have their critics, the apparent conflicts between them have not resulted in dire consequences that would force the Office to mimic the courts. The Office and patent community would similarly be able to absorb dual standards for the duty of disclosure without undue hardship. Indeed, between two dual standards for the duty to disclose, wise applicants and practitioners would simply follow the more burdensome of the two, thereby erring on the side of more disclosure.

The Office certainly has the power to promulgate a different standard, because Rules 1.56 and 1.555 on the one hand, and inequitable conduct doctrine, on the other, arise from completely different bodies of law. Rules 1.56 and 1.555 arise, apparently, from the Office's regulatory powers to "govern the [...] conduct of agents, attorneys, or other persons representing applicants or other parties before the Office."<sup>1</sup> In contrast, the

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<sup>1</sup> *Tafas v. Doll*, 559 F. 3d 1345, 1352 (Fed. Cir. 2009).

doctrine of inequitable conduct originates in the equitable doctrine of unclean hands.<sup>2</sup> These bodies of law do not have necessarily have anything to do with each other.

Indeed, although I prefer the Office’s proposal to adopt the *Therasense* standard for materiality, it is worth noting that a differing standard would benefit from the Office’s discretion to inflict discipline *other* than rendering patents unenforceable. As Judge O’Malley noted in her concurrence, the majority in *Therasense* maintains the Federal Circuit’s self-imposed inability to provide any other remedy for inequitable conduct than rendering an entire patent unenforceable.<sup>3</sup> In contrast, the Office suffers from no such self-imposed limitation. Indeed, not only is the Office not limited to rendering patents unenforceable as a result of Rule 1.56 and 1.555 violations, but it is not clear that the Office even has *that* power to void patents outside of conventional postgrant proceedings. Rather, the Office must, and should, tailor its discipline to the facts of the violation.

The other potential benefit of a dual standard would be that the Office would not be subjected to variations in case law as the Federal Circuit applies and interprets *Therasense*. History teaches a lesson here: although the Federal Circuit’s en banc decision in *Kingsdown* was heralded as a needed check on the “plague” of inequitable conduct, the Federal Circuit failed to rigorously or consistently apply the rule in *Kingsdown*, resulting in the need for *Therasense*.<sup>4</sup> The intra-circuit dispute about inequitable conduct between Federal Circuit judges, as indicated by the concurrence and dissent in *Therasense*, foreshadows a similar outcome after *Therasense*.

In view of the above, it would at least be better for the Office to simply restate the rule in *Therasense*, as quoted in proposed Rules 1.56 and 1.555, without explicitly citing the case name of *Therasense* itself. By simply quoting the standard, the Office will remain free to apply it according to its plain language, without being bound by the likely twists and turns in application of *Therasense* by the various judges at the Federal Circuit.

### **Reasons to Rescind or Further Weaken Rules 1.56 and 1.555**

While generally agreeing with the Office’s proposals to follow *Therasense*, I would go farther than the Office does in heightening the criteria for materiality: for several reasons, I would abolish the duty to disclose information altogether.

### **The Office Generally Does Not Police the Duty to Disclose**

First, and most importantly, the Office has repeatedly insisted that it generally cannot and will not police the duty of disclosure. For example, in 1997, well after the current version of Rule 1.56 was promulgated, the Office stated that “[it] no longer investigates fraud and inequitable conduct issues.” 62 Fed. Reg. 53131, 53165.

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<sup>2</sup> *Therasense, Inc. v. Becton, Dickinson & Co.*, \_\_\_ F.3d \_\_\_, 2011 WL 2028255 (Fed. Cir. 2011) (en banc) (slip op. 16)

<sup>3</sup> *Id.* (O’Malley concurring) (slip op. 7) (“I would overrule those cases and hold that, in the exercise of its discretion, a district court may choose to render fewer than all claims unenforceable, may simply dismiss the action before it, or may fashion some other reasonable remedy, so long as the remedy imposed by the court is ‘commensurate with the violation.’”).

<sup>4</sup> *Id.* (Bryson dissenting) (slip op. 5) (“Since that time there have been occasional departures from the holding in *Kingsdown* as to the requisite level of intent to establish inequitable conduct.”).

The Office bases its refusal to police the duty to disclose on, *inter alia*, the relevant statute of limitations, a lack of subpoena power, limited resources, and an alleged inadequacy for deciding questions of intent (as distinct from materiality). For the present comments, however, the reasons for the Office's refusal to police the duty of disclosure are irrelevant.

There are serious policy concerns with promulgating regulations that are not enforced. At the very least, the failure to police the regulations encourages disrespect for the Office and its regulations, including its Code of Professional Responsibility. The failure to police the regulations also creates incentives that would tempt even ethical and reasonable persons to violate the regulations. If the Office cannot enforce regulations, it should not promulgate them.

### **The Courts Separately and Independently Police the Duty**

Second, and complementary to the above point, the courts separately and independently police the duty to disclose. Indeed, the courts not only police the duty to disclose, but also define it (as in the Office's proposal to follow *Therasense*). If the courts are independently both defining and policing the duty to disclose, there is no reason for the Office to mimic them with paper regulations that the Office has no intention of enforcing. The Office may simply allow the courts to take on the entire burden of defining and policing the duty.

### **Many Foreign Patent Offices Have No Similar Duty**

Third, I understand that many patent offices around the world, including the EPO and JPO, either maintain no duty to disclose information or maintain a duty that is dramatically less burdensome than in the United States. The lack of such a duty to disclose information does not appear to have significantly impeded innovation in these other countries.

### **Examiners Systematically Ignore Information Disclosure Statements**

Fourth, it is an open secret that examiners routinely ignore information disclosure statements. For example, Lemley et al. conclude that "patent examiners effectively ignore almost all applicant-submitted art, relying almost exclusively on prior art they find themselves."<sup>5</sup>

One potential reason why examiners ignore such information disclosure statements is that both the submitted information and the statement itself (i.e. the form identifying the information by citation) are generally not submitted in text-searchable format. Thus, examiners under time and resource constraints might rationally prefer to search text-searchable prior art databases, which are readily available at their fingertips. The fact that examiners prefer to search prior art databases instead of overcoming the inconvenience of examining non-searchable images suggests that examiners find information disclosure statements to provide only marginal benefit in examining

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<sup>5</sup> "Do Applicant Patent Citations Matter? Implications for the Presumption of Validity," by Mark Lemley, Chris Cotropia, and Bhaven Sampat. [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1656568](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1656568)

applications (e.g. because examiners already find it relatively easy to reject almost all applications regardless of applicant submitted art).

The cost and burden that current and proposed Rule 1.56 impose on the patent bar, in terms of both compliance and non-compliance, far outweigh the apparently negligible benefit that it provides to the Office and public. The Office should not threaten to discipline persons associated with patent applications, and the courts should not threaten to destroy entire patents, simply because those persons failed to submit information that the Office ignores. If the Office insists on maintaining the duty to disclose, it can ensure that the benefit of the duty outweighs its cost by implementing policies that incentivize examiners to actually use information disclosure statements (e.g. by requiring information disclosure statements and submitted information to be submitted in, or converted to, a format that is convenient for examiners to search).

### **The Duty is Better Placed on the Examiner and Public**

Fifth, the duty exists in uneasy tension with the applicant's self-interest in obtaining broad patent protection and the practitioner's duty to represent clients zealously. Rule 10.84. As such, it requires applicants to harm themselves—an unnatural duty that even ethical and reasonable persons will feel tempted to violate, especially when violators are so poorly detected and disciplined.

It would be better to place such a duty on those with an interest in performing it: patent examiners, accused infringers, and the public. For example, examiners may make requirements for information under Rule 1.105 and generally any person may submit information through Rule 1.99 submissions, Rule 1.291 protests, ex parte and inter partes reexamination requests, and any other options made available through patent reform, including post grant review.

### **The Duty Needlessly Weakens Patents**

Sixth, concerns about compliance with the duty to disclose place a cloud over applications, once issued as patents, and can even do so during prosecution. These property rights are already uncertain enough because patents can be, and routinely are, invalidated in numerous ways, both in the Office and in the courts. Thus, even if shifting disclosure burdens from the applicant toward others results in some errors (i.e. because the applicant is better situated to know about some material information), these costs are outweighed by the benefits that abolishing the duty would obtain. Because of the scale of prior art and the complexity in patent law, errors will always be inevitable from a Patent Office with finite resources. As mentioned above, these errors can be avoided and corrected by shifting the burden to those with an interest in submitting information and by reconsidering patents in post-issuance proceedings at the Office and in the courts.

Respectfully submitted,

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