From: Kip Werking [e-mail address redacted]
Sent: Thursday, September 29, 2011 1:29 AM
To: AC58.comments
Subject: Updated Comments on Proposed Rules 1.56 and 1.555

Dear Mr. Bernstein,

Although I submitted my original comments on proposed Rules 1.56 and 1.555 by the September 19, 2011 due date, I later realized that there were several crucial issues that I had failed to address.

Accordingly, I have revised my comments (attached) and inserted discussions of several issues that I believe will be of interest to you and the Office in updating the regulations. These issues include:

1. a specific example of information that the Office would be interested in obtaining, even though the information does not satisfy by the "but-for-plus" standard
2. an explanation of how applicants and associated persons will rarely be able to know whether any evidence could rebut a prima facie case of unpatentability (and therefore "know" whether the information is material under proposed Rules 1.56 and 1.555)
3. an explanation of why concerns about "dumping" references and overburdening the examiner are greatly exaggerated
4. an explanation of how applications with many foreign counterparts can become trapped in cycles of reopening prosecution after issue fee payment under Rule 1.313
5. a discussion of how Rule 1.313 does not have any safe harbor, analogous to the certification in Rule 1.97(e), even though the safe harbor would make more sense after payment of the issue fee
6. a discussion of the "duty to investigate" under the Brasseler case, and why the practical difficulties of determining whether the "but-for-plus" standard is satisfied make the duty to investigate more relevant
7. a discussion of the duty to perform a reasonable inquiry under Rule 11.18 and its relationship to the duty to disclose information (i.e. are persons required to read every page of every submitted reference?)
8. an elaboration on how the Office is free to maintain a different standard for materiality than the Federal Circuit, and potential advantages of doing so

These and other issues are discussed more in the comments. If desired, and upon request, I can provide a copy that highlights the differences between my original submitted comments and the attached revised version.

I hope that I am submitting the updated comments timely enough to be published and considered by the Office.

Respectfully,

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September 28, 2011

Via E-mail to 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.

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 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 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. As discussed below, regarding Rules 1.4 and 11.18, it is common for applicants and practitioners to learn of a foreign search report indicating that information may be material, without substantively 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. 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)). Indeed, in subsection (h), Rule 1.56

(but not Rule 1.555) clarifies that the submission of information is not considered an admission of materiality.

Although the majority of information is volunteered to the Office in these manners, without a 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).

When no duty exists to submit information, persons may simply refrain from submitting the information to thereby avoid the burden. They may decide to refrain from submitting information even if the Office has a potential interest in it, such as information that satisfies the earlier standards for materiality under former versions of Rule 1.56, or information cited in a foreign search report without the person reviewing the information and knowing that it is material under the exacting standard of *Therasense*.

Consider the following example: a reference may not satisfy the "but-for" prong of proposed Rules 1.56 and 1.555, but still indicate a same inventor, author, assignee, keyword, or family of patent documents as another reference that does satisfy the "but-for" prong. In that case, the examiner, if possessing the information, may include the inventor name, author name, assignee name, keyword, or patent family information within a prior art search, thereby finding the related document that does satisfy the "but-for" prong. Clearly, the Office would be interested in obtaining information about references, as in the above example, that come close to satisfying proposed Rules 1.56 and 1.555 without actually satisfying either.

Note that the standard of *Thereasense* is so high that persons will be able to argue, in good faith, that they do not believe the vast majority of information to satisfy the standard. For example, even if information presents a prima facie case of unpatentability, persons will rarely, if ever, be able to certify that no rebuttal evidence exists that might rebut the prima facie case. Persons will generally be unaware of whether, in the sea of preexisting evidence, as well as evidence that the persons might generate (e.g. evidence of secondary considerations), any evidence exists that would rebut the prima facie case. Indeed, applicants and associated persons are not well positioned to determine the answer to the question of whether any rebuttal evidence might rebut a prima facie case. For example, it is impractical to expect persons to make a personal judgment call about whether evidence rebuts a prima facie case, instead of the examining corp., administrative patent judges, and/or federal judges doing so. Yet whether a person "knows" that information satisfies the "but-for" prong of proposed Rules 1.56 and 1.555, and thereby arguably commits inequitable conduct, turns upon this personal judgment call that the person is so poorly positioned to answer.

Indeed, a certification that information is material under the "but-for" prong of *Thereasense* is essentially a certification under Rule 1.313(c)(1) that at least one claim is unpatentable. How often do applicants admit that? Accordingly, without relaxing burdens on submitting information when no duty exists, it is likely that the proposed changes to Rules 1.56 and 1.555 would needlessly deprive the Office of information that the Office has a reasonable interest in obtaining.

As an example of the negative consequences of these burdens, 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.

In contrast, although the burdens of Rules 1.97 and 1.313 also apply when the duty exists, the duty itself (and the corresponding threat of discipline or inequitable conduct) should be enough to override concerns about the burdens. Thus, generally speaking, concerns about applicants refraining from submitting information, after a first action, to avoid these burdens will only be present when no duty exists to submit the information.

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. Rather, 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, thereby avoiding the negative consequences outlined above, including the intentional withholding of information of disputed materiality and the corresponding clouds placed over patents. The submission of information in these circumstances would be analogous to submission of information under Rule 1.501.

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):

> <u>(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 and must provide a brief explanation for the certification.</u>

~~(i)~~(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 multiple reasons. First, because the person 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). That compensation should be sufficient.

Second, concerns about overburdening the examiner with information are greatly exaggerated. An information disclosure statement that cites 100+ references may appear burdensome when considered in isolation. However, even a disclosure statement citing hundreds, or thousands, of references pales in comparison to the examiner's overarching duty to examine the application for compliance with the Patent Act. In performing that duty, the examiner will readily search databases, such as Google, that contain *billions* of references. The examiner must also examine the application with respect to prior art, such as prior uses and prior sales, that are not readily available to the examiner. It is absurd to suggest that the mere addition of a hundred or a thousand references to a database already containing billions of references, in addition to the other demands of examination, will unduly burden the examiner. In all cases, care must be taken to avoid shifting the burden of examination from the examiner to the applicant (analogous to the Office's attempt to require examination support documents). Concerns about overburdening the examiner are especially overstated when considering the reality that the Office retains a great interest in much information that does not satisfy the high standard of materiality in proposed Rules 1.56 and 1.555.

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.[1] The problem is that the burden to submit information after payment of the issue fee is disproportionately high. Specifically, applicants are limited under Rule 1.313 to one of three options: certifying that one or more claims are unpatentable (Rule 1.313(c)(1)), restarting examination by filing a request for continued examination (Rule 1.313(c)(2)), and restarting examination by expressly abandoning the application and filing a continuing application (Rule 1.313(c)(3)). MPEP 1308 and 2001.03.

[1] 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 requirement to certify that a claim is unpatentable is onerous on its face, although it is consistent with the Office's proposal to only create a duty to disclose information that actually renders a claim unpatentable. Nevertheless, for reasons discussed above, applicants often feel compelled to disclose information without a duty existing to do so. 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. The problem is aggravated by the fact that applicants and practitioners routinely submit information cited in related applications, such as foreign counterparts, without substantively reviewing the information in any depth. **If the application is a member of a sufficiently large family of related applications, then the application may literally become caught in a perpetual cycle of reopening prosecution because foreign offices release a new action or search report in at least one related application every time that the domestic application enters the window between payment of the issue fee and issuance of the patent.**

The government and service fees for filing an RCE or continuation application are also onerous. For example, the fee for an RCE is $930 for a large entity. In contrast, the fee for submitting information after the close of prosecution but before payment of the issue fee is merely $180. Rule 1.97(d). To pay the smaller fee, the applicant must simply certify that the information was generally not known more than three months prior to submission. Rule 1.97(e). However, the option to certify is unavailable after payment of the issue fee, **even though the policy behind the certification option remains regardless of whether the issue fee is paid (indeed, the policy is more applicable after payment of the issue fee)**. Even if the person first learns of the information one day after paying the issue fee, he is still limited to the disproportionate burden of Rule 1.313(c)(1)-(3) outlined above. RCEs and continuing applications also obliterate patent term extension under 35 U.S.C. 154(b)(1)(B).

In view of the above, it would simply be better for persons to be under to no duty to submit information after payment of the issue fee. 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 Should Clarify the Duty to Investigate and the Duty to Make a Reasonable Inquiry Under Rules 1.4 and 11.18 When Submitting Information Disclosure Statements

It remains unclear exactly how much a person must review information submitted to the Office in an information disclosure statement. Rule 11.18 places a duty on practitioners to make an "inquiry reasonable under the circumstances" when submitting papers. See also Rule 1.4.

In 2007, former director of the Office of Enrollment and Discipline Moatz argued that the "inquiry" language in Rule 11.18 (then in Rule 10.18) required that "[p]ractitioners submitting papers must read each paper submitted to the Office before it is submitted." Moatz further stated that "[e]ach submitted paper must be read in its entirety."[2] The Federal Circuit has not embraced that strict interpretation of the duty to disclose in the context of inequitable conduct. *Innogenetics v. Abbott Laboratories*, 512 F.3d1363, 85 USPQ2d1641 (Fed. Cir. 2008). Nevertheless, to my knowledge, the "inquiry" language in Rule 11.18 has not relevantly changed.

Similarly, in *Brasseler v. Stryker Sales Corp.*, the Federal Circuit has held that the doctrine of inequitable conduct creates a duty to investigate, which is limited in the following manner:

> There is no need for an attorney to pursue a fishing expedition to obtain information. Counsel can reasonably rely on information provided by the client, unless, as here, there is reason to question the accuracy or completeness of the information or to doubt the adequacy of the client's own investigation into material facts.[3]

However, the Federal Circuit has not applied the rule in *Brasseler* in any consistent manner. Further, *Therasense* does not address the duty to investigate information, even though the "but-for-plus" standard of materiality is so high that it makes a duty to investigate more appropriate. It remains unclear whether any duty to investigate exists in either inequitable conduct jurisprudence or under Rules 1.56 and 1.555.

As mentioned above, it is often impractical for persons to review all information submitted to the Office. The information may be in a language other than English. Even if translations are possible, machine translations may be inaccurate or indecipherable, and human translations may be cost prohibitive. Further, the sheer quantity of information may make any substantive review of the information impractical. It is not uncommon, for example, for practitioners to submit information disclosure statements citing 50-200 references that were cited by foreign offices in counterpart applications.

In view of the above, the Office should clarify whether Rules 1.56 and 1.555 create any duty to investigate information that may be material. As explained above, for virtually all information that persons will consider submitting, the person will be unaware of whether the information actually satisfies the "but-for" standard of *Therasesense*. Indeed, persons will have no means of knowing whether any evidence exists, or could be created, to rebut a prima facie case of unpatentability. Further, for reasons outlined in this section, it is generally impractical for persons to substantively review most references in any detail. In each of these cases, the Office should clarify whether Rules 1.56 and 1.555 create any duty by persons to investigate whether information that might

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[2] http://www.patentlyo.com/patent/MoatzHarry_presentation.pdf (discussed at http://www.patentlyo.com/patent/2007/10/ethical-duties-.html?cid=86772896).
[3] *Brasseler v. Stryker Sales Corp.*, 267 F. 3d 1370, 1382-1383 (Fed. Cir. 2001).

satisfy the high standard of materiality in *Therasense* actually does, in fact, satisfy the standard.

To be clear, I do not advocate creating any duty to investigate, which would be overly burdensome and extremely difficult to apply in a fair and predictable manner. Rather, when submitting information to the Office, the only "inquiry reasonable under the circumstances" under Rule 11.18, beyond the certifications of Rule 11.18(b)(i)-(iv), should be an inquiry to ensure that information other than intended information is not inadvertently submitted. In other words, the inquiry should be to ensure that the reference cited in a foreign search report, or supplied by the client, is the same reference submitted to the Office (e.g. by comparing identifying information between what the person received and what the person is submitting). Any further duty to read each submitted paper in its entirety is impractical, unduly burdensome, and not enforced by the Federal Circuit.

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 Ruled 1.56(b) and 1.555(b).

Although the omission may have been innocent, the Office should restore the original 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 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. Because the time has already lapsed for filing a petition for certiorari in *Therasense*, and apparently 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). Yes, the Federal Circuit rejected the Office's position, but the holding in *Thereasense* does not control how the Office defines its own Rules when regulating conduct before the Office. On this issue, the Office is simply free to respectfully disagree with the Federal Circuit.

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. 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."[4] In contrast, the doctrine of inequitable conduct originates in the equitable doctrine of unclean hands.[5] These bodies of law do not have necessarily have anything to do with each other.

For over a decade, the Federal Circuit has applied standards of materiality in inequitable conduct cases that deviated from whatever the current version of Rule 1.56 set forth. Further, the Office has always retained the power under Rule 1.105 to require applicants to submit information beyond that defined in Rule 1.56. MPEP 704.12(a). No dire consequences resulted.

Similarly, dual standards of materiality 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. 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 (while being careful to avoid "dumping" or violating Rule 11.18).

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.[6] Because the Federal Circuit limits itself to

[4] *Tafas v. Doll*, 559 F. 3d 1345, 1352 (Fed. Cir. 2009).
[5] *Therasense, Inc. v. Becton, Dickinson & Co.*, ___ F.3d ___, 2011 WL 2028255 (Fed. Cir. 2011) (en banc) (slip op. 16)
[6] *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.'").

such a drastic remedy, it similarly limits itself to a standard of materiality in *Therasense* that is drastically high.

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. Because the Office is free to impose discipline less draconian than destroying entire patents, the Office is correspondingly free to define materiality in a broader sense than the Federal Circuit. Indeed, doing so may in some cases result in discipline that is less harsh, and fairer, than the atomic bomb of inequitable conduct. In all cases, 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*.[7] 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.

<u>Reasons to Rescind or Further Weaken Rules 1.56 and 1.555</u>

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. Indeed, although one or more may exist, I am not aware of a single instance where the Office of Enrollment and Discipline found a violation of current Rule 1.56 since its promulgation.

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

[7] *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.").

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."[8]

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

[8] "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

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 Burden 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 burden on those with an interest in satisfying 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 Costs of the Duty Outweigh the Benefits

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 quantity of prior art and the complexity of 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 postgrant proceedings at the Office and in the courts when necessary.

Respectfully submitted,

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