Comments of James Toupin in response to
the US Patent and Trademark Office's Notice of Proposed Rulemaking,
Revision of the Duty To Disclose Information in Patent Applications and
Reexamination Proceedings,
Docket No.: PTO–P–2011–0030

These comments, responding to the U.S. Patent and Trademark Office's notice of proposed rulemaking[1] on amending its Rule 56, [2] are submitted with some hesitancy. The Office's decision to request comments on the question a second time may, however, reflect a desire for additional perspectives on the question. Perhaps, then, a former civil servant executive of the agency,[3] may assist by bringing to bear some additional technical and policy issues that have not yet been fully treated.

To judge by the current notice's description of prior comments, the Office received a relatively contained set of views in earlier stages of this rulemaking. That range surely reflects an understandable relief among patent practitioners that the risks attaching to filing in the USPTO have lessened. The present comments do not seek to weigh how that reaction, or other related interests of stakeholders, should factor in the USPTO's final decision.

Rather, they seek to assure that the agency's rationale for adopting a course of action addresses a wider scope of concerns. These comments will focus on the changes that the AIA makes in inequitable conduct law, the differing roles and flexibilities of court and agency, and the relationship between practitioner ethics rules and the duty of disclosure. The Office is to be commended for issuing a second notice to entertain additional comments.

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[1] Notice of proposed rulemaking, *Revision of the Duty To Disclose Information in Patent Applications and Reexamination Proceedings,* 81 Fed. Reg. 74987 (October 26, 2016).

[2] The notice encompasses 37 C.F.R. § 1.56 (a),(b) and 37 C.F.R. § 1.555 (a),(b). These comments are directed principally to subsections (b) of those rules and will refer to the rules collectively as Rule 56.

[3] Currently an adjunct professor at Washington College of Law, American University, and an intellectual property mediator, the submitter was general counsel of the USPTO from 2001 to his retirement from federal service in 2010. Some of the issues discussed in these comments are also touched upon in Davidow and Toupin, *Patent Related Misconduct Issues in U.S. Litigation* (Matthew Bender 2016).

1. The Question of *Therasense*'s Vitality

A threshold question is whether the *Therasense* decision continues to define the materiality standard for inequitable conduct in cases governed by the Leahy-Smith America Invents Act (AIA). Although the proposed rules no longer refer explicitly to *Therasense*, harmonizing the agency's regulatory standard for the duty of candor with the court's inequitable conduct standard is the key driver for the rulemaking. There is, however, reason to question whether *Therasense* will state the inequitable conduct standard when changes wrought by the AIA are taken into account.

In increasing the stringency of the proofs needed to establish the inequitable conduct defense, the Federal Circuit expressly relied on the fact that, unlike other errors committed in patent prosecution, the Patent Act provided no avenue for correcting such conduct after prosecution of an application is closed.[4] The reissue procedure, the court had stated, cannot be used to cure inequitable conduct in the original application prosecution.[5] This was because under pre-AIA 35 U.S.C. § 351 reissue was only available to correct errors that arose "without deceptive intent."

The AIA changes whether patentees can resort to the USPTO to cure prior inequitable conduct. First, in a technical amendment, section 20(d) of the AIA deletes the phrase "without deceptive intent" from the reissue statute.[6] Although this provision does not explicitly address the use of reissue to cure inequitable conduct, it changes the basis on which the Federal Circuit previously held that reissue could not be used to expunge inequitable conduct.

More directly, AIA section 12, codified at 35 U.S.C. § 257, provides for a post-issuance procedure to cure inequitable conduct.[7] Through supplemental examination which a patent owner can use to ask the USPTO to "consider, reconsider or correct information believed to be relevant to the patent."[8] Under subsection (c), "A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent."[9] Since the USPTO under subsections (a) and (b) conducts a supplemental examination to decide whether to reexamine the patent, the filing operates as a cure of inequitable conduct even if the USPTO (whether or not correctly) decides that it does not present a substantial new question of patentability.

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[4] *Therasense, Inc. v. Becton, Dickinson and Co.,* 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc).
[5] *Hoffman-La Roche Inc. v. Lemmon Co.,* 906 F.2d 684, 688 (Fed. Cir. 1990).
[6] AIA § 20(d), 125 Stat. 333, *amending* 35 U.S.C. § 251.
[7] 125 Stat. 325.
[8] 35 U.S.C. § 357(a).
[9] 35 U.S.C. § 357(c)(1).

Accordingly, the AIA now provides the opportunity for correction whose prior lack the Federal Circuit stated justified its change in the materiality standard. But this is not all. Responding to contrasting analogies offered by the dissenters, the majority in *Therasense* stated, "While but-for materiality may not be required in every context, it is appropriate for inequitable conduct in light of the numerous adverse consequences of a looser standard."[10] The decision is clear on the but-for test's link to the scope of unenforceability: "*Because* inequitable conduct renders an entire patent (or even a patent family) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim."[11] The AIA, however, not only changed the availability of cure, but may also have radically altered the adverse consequences of a finding of inequitable conduct.

The court of appeals in *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*[12] held that 35 U.S.C. § 288 required that a finding of inequitable conduct prevents the enforcement not only of specific claims implicated by the misconduct but also of entire patents and, in some cases, families of patents. The first sentence of section 288 then provided, "Whenever, without deceptive intent, a claim of patent is invalid, an action may be maintained for infringement of a claim of the patent which may be valid." The *J.P. Stevens* court interpreted this provision, first promulgated in the 1952 act, as abrogating for invalidity holdings the common law rule that the invalidity of any claim rendered the entire patent invalid, but as continuing that rule for inequitable conduct because the provision excluded cases of "deceptive intent."

Section 20(h) of the AIA amended 35 U.S.C. § 288 by striking "without deceptive intent,"[13] the phrase on which the *J.P. Stevens* court relied. Accordingly, under the reasoning of *J.P. Stevens*, this change in the statute should abrogate the so-called common law rule of the scope of effect of inequitable conduct, as original section 288 did for invalidity. The legislative history does not discuss this change, noting only that section 20 "sets forth technical amendments consistent with this Act."[14] Litigants may therefore have ignored their potential significance. Since these amendments apply only to proceedings begun at least a year after enactment of the AIA,[15] it is unsurprising the court of appeals has not yet addressed their significance.

If this view of the AIA's effects on the unenforceability remedy for inequitable

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[10] *Therasense*, 649 F.3d at 1295.
[11] *Id.* at 1292 (emphasis added).
[12] 747 F.2d 1553, 1561–62 (Fed. Cir. 1984).
[13] 125 Stat. 334.
[14] H. Rep. No. 112-98, at 82 (2011). The rubric "technical amendments" might suggest they were not expected to have important effects. The amendments, however, deleted the same phrase wherever found in the Patent Act, reflecting an intent to have a systemic and consistent impact on the law.
[15] AIA § 20(1), 125 Stat. 335.

conduct is correct, the AIA has undone the "atomic bomb"[16] nature of the unenforceability remedy that was central to *Therasense*. The AIA has now undone the procedural limitations, and indeed perhaps the principal other consequences, on which the en banc majority relied for rejecting the minority view of the proper materiality standard.[17] The question is at least open whether the stricter materiality standard should under *Therasense*'s reasoning continue to apply to inequitable conduct.

It seems premature to premise new administrative action on the assumption that the Federal Circuit will not reconsider *Therasense*.[18] If the Office conforms to the *Therasense* standard now, it will eliminate the option, when the court takes up these questions, of the court's conforming its standard to the Office's. If the Office delays amending its rules, it may facilitate the court's addressing whether changes made by the AIA implicate the inequitable conduct doctrine as a whole.

2. The Adequacy of But-For Materiality and the Distinct Roles of Court and Agency

The Office's historic reasoning concerning but-for materiality gives reason to doubt whether conforming its materiality definition to that of *Therasense* will support quality patent examination. [19] In 1992, the Office adopted a more precise materiality definition, rather than the vaguer standard previously used, to give

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[16] *Therasense,* 649 F.3d at 1288, *quoting Aventis Pharma S.A. v. Amphastar Pharm., Inc.,* 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

[17] A case law development also seems to undercut the court's reliance on a more minor factor -- inequitable conduct as a ground for fee awards under 35 USC § 285. *Therasense*, 649 F.3d at 1288. *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014), overturned as unduly restrictive the Federal Circuit's standards for declaring cases exceptional under section 285.

[18] Whether the court would need to sit *en banc* to do so, as the Office suggests, is more complex. *Therasense* being expressly responsive to aspects of the statute, a panel could hold that, those aspects being altered, *Therasense* no longer controls. Alternatively, it could hold that, *Therasense* being an *en banc* decision, the whole court needs to assemble to consider the impact of statutory change.

[19] The changes outlined above in the Patent Act are capable of having greater influence on oversubmission than any particulars of the materiality standard. The disproportion that has prevailed between the consequences of obtaining an invalid claim and of committing inequitable conduct has surely been a more driver of overinclusive filings than any materiality standard. The former has been correctable; the latter, until the AIA, has not. The former has no consequences for other claims, while the latter has to date rendered all claims, even other patents, unenforceable. Particularly when carefully examining relevant prior art to assure that the examiner considers only the most material art, under whatever standard, adds cost to prosecuting an application, practitioners would rationally oversubmit.

applicants better guidance.[20] The Office explicitly rejected a but-for materiality test precisely because it would not give an examiner what was needed for adequate examination.[21] Unfortunately, the Office's revised materiality definition was not given an opportunity to have its full effect. Until *Therasense* the Federal Circuit continued also to apply the earlier, vaguer standard.[22] Where the two standards might differ, applicants were bound to follow the broader, vaguer standard.

The Office's current Federal Register notice, however, cites the *Therasense* court's contention that a but-for standard would reduce oversubmitting of prior art. For the agency to adopt that judgment in its reasoning for changing its own standard would be particularly problematic when the court's refusal to adopt the Office's materiality standard may have trumped the Office's effort to clarify the duty. Moreover, the Office has not hitherto treated overinclusive submissions as sufficient reason to adopt a but-for standard. In fact, the agency stated in adopting current Rule 56 that it expected applicants to submit information beyond what the rule required in part in order to strengthen issued patents.[23] If the Office's *Therasense* brief observed that overinclusive submissions detract from efficiency, it did not suggest but-for materiality in preference to its current standard.[24] If the Office now has altered its view, it should say why. If the Office does not have reason to alter its view, it should either say how otherwise a change in materiality standard will advance patent quality or why consistency with inequitable conduct outweighs quality concerns.

Nor should the Office, without further reasoning, be concerned only, as the *Therasense* court seems to have been in its analysis of examination, with the burdens of oversubmitting. The distinction between submissions that would create a prima facie basis for rejection, required by the current rule, and submissions but for which a claim would be rejected, is not insignificant. What has been lost when

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[20] *See* H.F. Manbeck, Jr., "Evolution And Future Of New Rule 56 And The Duty Of Candor: The Evolution And Issue Of New Rule 56," 20 AIPLA Q. J. 136 (1992).
[21] *See* Notice of Proposed Rulemaking, *Revision of the Duty To Disclose Information in Patent Applications and Reexamination Proceedings*, 57 Fed. Reg. 2021 (January 17, 1992) ("The suggested 'but for' standard would not cause the Office to obtain the information it needs to evaluate patentability so that its decisions may be presumed correct by the courts. If the Office does not have needed information, meaningful examination of patent applications will take place for the first time in an infringement case before a district court.")
[22] *See Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (applying 1977 version of Rule 56), *cited in Therasense*, 649 F.3d at 1294.
[23] 57 Fed. Reg. 2021 (January 17, 1992).
[24] A couple of years before the AIA, I held talks on the USPTO's behalf with bar groups to consider legislative changes to inequitable conduct. Though the Office was then pursuing rulemaking in part to deal better with large prior art filings, the agency's political appointee leadership, as I advised the meetings, instructed me not to agree to a but-for materiality standard. The rationale was that such a standard would fail properly to make of record the basis on which a patent should be granted.

the applicant decides not to submit such information? The applicant has not put on record the information or argument that would traverse a rejection. It has not, for example, adduced the secondary considerations that would overcome an obviousness rejection, or presented a clarifying interpretation of the claim terms.

Such effects do not seem to advance patent quality. In the latter case, for instance, the Office will have issued a patent with ambiguous claims that could have been clarified during examination and thus have given to the public better guidance as to what constitutes infringement. This result seems contrary to what the Office has regarded as quality examination[25] and may put additional burdens on the Office and the public. The failure of the applicant and examiner to engage on such prior art may lead to third parties filing for review or reexamination of the patent based on the omitted prior art. Indeed, the patentee itself may later seek reexamination. Those submissions, and extra proceedings before the Office, might have been avoided had the clarifying examination occurred during the original application process.

These issues factor not at all in the *Therasense* decision. It is not hard to see why not. The court there was concerned with "basic fairness" to the patentee, with assuring that the "remedy imposed by a court of equity should be commensurate with the violation."[26] Accordingly, it dismissed the first prong of Rule 56 (concerning information that establishes a prima facie case) as inadequate for its purposes because "[u]nder this standard, inequitable conduct could be found based on an applicant's failure to disclose information that a patent examiner would readily agree was not relevant to the prosecution after considering the patentee's argument."[27] It did not consider whether argument that would clarify relevance for an examiner would also do so for competitors, because such concerns were no part of its analysis of the fairness of the inequitable conduct remedy to patentees.

It is not similarly evident that the USPTO in establishing rules for the application process should abandon its historic range of concerns. As Director Lee has stated,

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[25] *See* MPEP ¶ 2173.02 ("If the examiner considers applicant's arguments and/or amendments to be persuasive, the examiner should indicate in the next Office communication that the previous rejection…has been withdrawn and provide an explanation as to what prompted the change in the examiner's position (e.g., by making specific reference to portions of applicant's remarks). By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722…(2002), a clear and complete prosecution file record is important in that '[p]rosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process.'")

[26] *Therasense*, 649 F.3d at 1292, *quoting Columbus Bd. of Educ. v. Penick,* 443 U.S. 449*,* 465 (1979).

[27] *Id.* at 1294.

> We strengthen our patent system most effectively when we take advantage of what each branch [of government] can do best….Every one of our examiners understands that issuing patents of clear scope is more important than ever before, so inventors can better understand the scope of their rights, and so others including competitors can have the information they need to make informed business decisions such as where to invest limited research and development dollars and when to take a patent license.[28]

Adopting a materiality definition used by another branch of government for a different purpose may detract from efforts toward that goal. Despite the court's observations about examination quality, its justifiably larger concern was the cost and delay imposed on patent cases by usually unsuccessful inequitable conduct claims.[29] The Office's rules are properly directed to the distinct goal of assuring the soundness of examination in process and the record made therein.

All such judgments by the Office require balancing competing values. Practitioners have historically been concerned about rules that may lead them to make representations that create estoppels.[30] Practitioners' anxiety reflects the risk they may make arguments during prosecution only to find in litigation that different arguments would have preserved greater claim scope. From a USPTO operational perspective, a duty of disclosure that calls forth additional Office actions may have a positive value in clarifying claims but a negative value in extending pendency. Simply deferring to the court's rule for inequitable conduct does not engage in the cost-benefit analysis that would adequately weigh the salient factors.

3. Alternative Approaches Available to the Office

The USPTO can consider a wider variety of approaches than are contained in the holding of *Therasense* or in the current proposed rule. The decision itself may point a way toward more effective means of mitigating the quality impact of large submissions. More broadly, the Office should examine whether using the greater regulatory flexibilities that it has may enhance examination better than conforming to a materiality standard geared to the sanction of unenforceability.

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[28] Remarks by Director Michelle K. Lee at The Center for Strategic and International Studies (CSIS) Patent Reform Forum, https://www.uspto.gov/about-us/news-updates/remarks-director-michelle-k-lee-center-strategic-and-international-studies.

[29] *See Therasense*, 649 F.3d at 1293 ("While this court respects the PTO's knowledge in its area of expertise, the routine invocation of inequitable conduct in patent litigation has had adverse ramifications beyond its effect on the PTO.")

[30] *Cf. Tafas v. Doll,* 559 F.3d 1345, 1358 (addressing argument that additional filings will reduce patent value due to risk of prosecution history estoppel), *vacated as moot* 586 F.3d 1369 (Fed. Cir. 2009)

a. Addressing the Burying of References

Of greater concern for quality than oversubmitting *per se* has been obscuring the most on-point references in a submission of a large body of marginally pertinent art. On that point, the *Therasense* decision suggests a way for the Office to take action of which the proposed rulemaking fails to take advantage. The Office's ability to address this problem has seemed limited by the Federal Circuit's decision in *Molins PLC v. Textron, Inc.,*[31] where the court found the applicants had not affirmatively misrepresented the reference and treated the fact that the examiner had initialed the reference as refuting the allegation of deceptive intent. The *Therasense* court, in contrast, recognizes the impossible situation that unduly burdensome submissions puts on examiners, quoting the ABA Section on Intellectual Property Law for the observation that "'Applicants disclose too much prior art for the PTO to meaningfully consider…'"[32]

Currently, the MPEP provides that an examiner's initialing of references indicates a level of scrutiny similar to what he or she would give information found through a search.[33] When the ABA and the court of appeals recognize that such initialing is meaningless in the face of massive filings, the Office may want to reconsider the false assurance that is conveyed when examiners routinely check off prior art submissions. Making explicit that an examiner's check does not excuse deliberate obscuring of material art might go farther to reducing massive submissions than a change in the materiality standard.

Massive filings may also reflect a lack of due diligence. In a 2006 proposed rulemaking, the USPTO interpreted the duty of inquiry now codified in 35 C.F.R. §§ 11.18(b)(2) and 11.18(b)(2)(i) to require submitters to have reviewed the references to assure that the submission does not unnecessarily delay or add to the cost of examination.[34] The Office could amend its rules or add language to the standard information disclosure statement to make this duty more explicit. Or it might amend the MPEP to reiterate that an examiner's check does not necessarily excuse or mitigate a submitter's failure of the duty of care.

Regardless of whether the rules or MPEP are amended, truly massive filings would appear on their face not to reflect such review, at least where they are submitted without any commentary on the relevance of individual items. The Office has, wisely

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[31] 48 F.3d 1172 (Fed. Cir. 1995).
[32] *Therasense*, 649 F.3d at 1289, *quoting* ABA Section of Intellectual Property Law, *A Section White Paper: Agenda for 21st Century Patent Reform* 2 (2009).
[33] Manual of Patent Examining Procedure ¶ 609.05(b).
[34] Notice of proposed rulemaking, *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 Fed. Reg. 3808, 3809 (July 10, 2006). *See also* In the Matter of William H. Bollman, Proceeding No. 2010-40 (USPTO 2016), https://e-foia.uspto.gov/Foia/RetrievePdf?system=OED&flNm=0658_DIS_2011-10-19

in my view, been reluctant to use the heavy hand of ethics discipline. It might, however, consider specifically encourage examiners, when faced with such submissions, to respond not with a substantive Office action, but rather with an inquiry as to the criteria for the selection of submitted art.[35] Such a step would allow practitioners to narrow unduly expansive submissions, to the benefit both of professional legal practice and of effective examination.

b. The Greater Flexibility Available to the Office

As noted above, the *Therasense* court recognized that its materiality standard might not be required in all contexts but held that but-for materiality was appropriate in view of the severity of the unenforceability sanction. The Federal Circuit[36] appears not to have regarded it as open to it to mitigate the scope and severity of unenforceability (though that option may now be open to it after the AIA). Such an option is, however, clearly open to the USPTO.

One approach would be to address the uncosted externalities that arise when an applicant does not disclose information that would create a prima facie case of unpatentability. A failure to submit information that the current Rule 56 would require can impose costs on third parties, as well as degrading the quality of examination. Thus, for example, a potential infringer may need to seek inter partes or post-grant review or reexamination to have the Office consider prior art, which it would not do if the examiner had addressed the art in original examination.

The Office might consider, where such examination did not occur because the applicant deliberately withheld the art, providing by rule for the patentee to reimburse the petitioner's filing fee. Alternatively, the Board might be authorized to consider less than dispositive adverse inferences.[37] Although the cost of litigating inequitable conduct has been a problem in district court litigation, the Board's

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[35] Under 37 C.F.R. § 1.105, whether a search was conducted and what was searched are given as an example of information examiners may request as "reasonably necessary to properly examine or treat the matter." *See Star Fruits S.N.C. v. United States,* 393 F.3d 1277 (Fed. Cir. 2005) (affirming rule).

[36] Other members of the court did not take up of Judge O'Malley's suggestion to consider a more flexible remedy. *Therasense*, 649 F.3d at 1299. An exception to this generalization may be the distinction the *Therasense* majority draws between inequitable conduct and Supreme Court precedents on unclean hands. It characterizes them as distinct from inequitable conduct in part because they involve dismissal of suits rather than unenforceability. *Id.* at 1287. *Therasense* does not purport that its inequitable conduct standard sets forth the only basis on which a court may find misconduct before the Office. *Id.* ("Though inequitable conduct developed from these cases, the unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases.")

[37] *Cf.* 37 C.F.R. § 11.18(c) (violation of subsection (b)(2) can lead to prohibition of presenting or contesting an issue.)

ability to control discovery should mitigate such potentialities in inter partes proceedings. Adverse inferences might also, for example, be a suitable approach in derivation proceedings when there is evidence of misconduct in allegations relating to inventorship.[38]

Therasense adjusted the materiality standard to fit the severe consequences of inequitable conduct findings. The Office, however, has it in its power to mitigate in non-draconian ways the deleterious effects that applicants impose on others by deliberately trying to avoid having examiners address troublesome issues. The courts have recognized that counsel have beyond the specifics of particular statutory sanction schemes a "general duty of candor and good faith required to protect the integrity of the entire judicial process."[39] It would anomalous for the courts to insist that the USPTO conform its standards for candor to a sanction scheme it does not administer that is conceived as punishing the most egregious infractions. Nor have they done so. A rulemaking that conforms the examination standard of materiality to the unenforceability standard should also explain why the agency did not adopt more measured sanctions rather than change its standard.

This is all the more the case if the effects of the AIA are taken into account. Before the AIA, the Office was largely dependent on the results of inequitable conduct defenses to learn of violations of the duty of candor. However interpreted, the AIA both lessens the judiciary's role in supporting norms of candid patent prosecution and, through post-grant procedures, increases the occasions on which the Office may learn of violations. The AIA can be said to shift to the USPTO the onus for creating more nuanced ways to incentivize trustworthy patent applications.

4. Effects on Ethics Requirements

The Office's disavowing its current materiality standard would create complex and anomalous interactions with its ethics rules for practitioners. Rule 11.303(d) adopts the parallel provision of ABA Model Rule of Professional Conduct 3.3(d), requiring disclosure of "all material facts known to the practitioner that will enable the tribunal to make an informed decision, whether or not the facts are adverse." The open-ended phrase concerning enabling the tribunal to make an informed decision makes no sense if the only material facts are those that would require the tribunal to decide against the practitioner's submission. Subsection (e) adds the gloss that practitioners are required to comply with the agency's duties of disclosure. These two subsections read in harmony under current Rule 56, which implicitly defines

[38] *Cf. Jaskeiwisz v. Mossinghoff*, 822 F.2d 1053 (Fed. Cir. 1987).
[39] *Va. Innovation Scis., Inc. v. Samsung Elecs. Co*., 983 F. Supp. 2d 713, 756 (E.D. Va. 2014)(notice to court of related proceedings), *relying, inter alia, on Chambers v. NASCO, Inc*., 501 U.S. 32 (1991), *United States v. Shaffer Equip. Co*.,11 F.3d 450 (4th Cir. 1993).

the material facts that would enable an examiner to make an informed decision. [40]

Adopting the *Therasense* materiality standard would disrupt this harmony. *Therasense* did not purport to define what facts would help an examiner make an informed decision, but rather what omission would justify an unenforceability sanction. The court characterizes the second prong of Rule 56 as "broadly encompassing anything that would be marginally relevant."[41] The provision may have seemed so broad to the court when considered in the light of what omissions would justify unenforceability. The second prong does not appear broader than the ethics requirement applicable in states that have adopted Model Rule 3.3. The Office's disclosure rules would no longer require submission of facts that it has for decades regarded as needed to enable an informed decision and that states require in other ex parte proceedings.

It would be difficult to say any longer that subsection (e)'s definition of materiality glosses for Rule 56 proceedings[42] the materiality standard in subsection (d). Soon after harmonizing its ethics rules with the ABA Model Rules,[43] the Office would have to articulate a departure from the approach of those rules, perhaps by explicit exception to the coverage of subsection (d). At least one state has held that ABA rule 3.3(d) requires attorneys in ex parte practice before other government agencies to submit all "adverse" information.[44] If in adapting to the but-for materiality test the Office redefines materiality in subsection (d), it should explain why the same ethics rule should lead to a narrower materiality standard before the USPTO than, as in

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[40] Insofar as the ethics rules incorporate Rule 56 by reference, the Office's statement that the proposed rule is not substantive is questionable. The Office is well-advised to continue to follow substantive rulemaking procedures.

[41] *Therasense*, 649 F.3d at 1294. The Office can, of course, without revoking it provide guidance to practitioners if they are uncertain what information it encompasses. *See, e.g., Environ Prods. v. Total Containment, Inc*., 43 U.S.P.Q.2d 1288, 1291 & n.1 (E.D. Pa. 1997)(relying on MPEP in interpretation of Rule 56), *citing Molins PLC*, 48 F.3d at 1180 n.10.

[42] Rule 303(d) covers other USPTO ex parte proceedings that Rule 56 does not, presumably including pre-initiation phases of patent post-grant proceedings to the extent that statute or rule prevents reply by the patent owner.

[43] *See Changes to Representation of Others Before The United States Patent and Trademark Office*, 78 Fed. Reg. 20179, 20180 (May 3, 2013)("The USPTO is adopting professional conduct rules consistent with the ABA Model Rules and the professional responsibility rules already followed by 50 U.S. jurisdictions, *i.e.,* the District of Columbia and 49 States, excluding California.")

[44] *See* Alabama State Bar Formal Opinion 1993-06, https://www.alabar.org/resources/office-of-general-counsel/formal-opinions/1993-06/ (last accessed December 10, 2016).

that opinion, before the Social Security Administration.[45]

The Office's departing from the approach of ABA Model Rule 3.3 might pose problems in states that apply the Model Rules. Similar questions concerning counsel's duties in ex parte proceedings can arise in litigation, for example when plaintiffs seek temporary restraining orders. Courts applying state ethics standards, as well as state bars, may be put to the question of whether they should in ex parte proceedings involving intellectual property conform to the Office's narrower definition of materiality. Or members of the patent bar may find themselves misinterpreting their duties toward other tribunals.

At the same time, it should be recognized that changing the Rule 56 materiality standard but not that of Rule 303(d) would create other unfortunate dynamics. A practitioner would be under an ethical obligation to disclose to the Office information that others assisting in the application would not be under an obligation to disclose. This discrepancy could lead to clients' not informing their counsel of significant facts to assure they do not trigger counsel's duty to the Office.

If both rules are aligned to *Therasense*, new ethics quandaries may arise about the duty to keep client confidences. Under 37 C.F.R. § 11.106(a), (c), an attorney is excused from the ethics requirement to keep client confidences if the client has communicated to the attorney information that both the attorney and client are required to submit under applicable duty of disclosure rules. Conversely, a practitioner's deliberate failure to disclose material information can constitute an ethics violation under 37 C.F.R. § 11.303(d), (e).

Rules 106 and 303 work relatively smoothly together under the current regime. To convince a reluctant client that the rules require information to be submitted, the lawyer need only convince the client that the information might give rise to an Office action that the applicant might be able to traverse. Under the new rule, however, a practitioner would have to persuade a recalcitrant client that the troublesome information would create a basis for a rejection that could not be overcome.

This seems a less tenable position for a practitioner, though others can speak best to which interchange better contributes to ethical practice and cooperative attorney-client relationships. Such a practitioner may find herself needing to argue to the client that she can think of no nonfrivolous argument in favor of patentability over

[45] If the Office conforms "material" in Rule 56 to *Therasense* and in Rule 303(d) to Rule 56, it seems to follow that that definition would apply to trademark cases. The *Therasense* court notes that but-for materiality applies to cancellation of mark registrations for fraud on the Office. 649 F.3d at 1295. *But see Fair Isaac Corp. v. Experian Info. Solutions, Inc.,* 650 F.3d 1139 (8th Cir. 2011)*, discussed in* T.H. Davis and L. Brenner, "Allegations of Fraudulent Procurement and Maintenance of Federal Registrations Since *In re Bose Corp.*," 104 The Trademark Reporter 933, 941-42 (2014), as creating a split in case law on but-for materiality in trademark cases.

the confidential information in order to claim that the duty to disclose applies. Short of that, regarding the information as likely to lead to a rejection, she may see herself as obliged to submit the information notwithstanding the client's recalcitrance. If the claims are allowed, the attorney will have violated an ethical prohibition. If the information is withheld and claims allowed, an invalidity holding in later litigation may show that it would have been dispositive. Though inequitable conduct mat not have been raised, the practitioner may see the court's holding as entailing she failed an ethical duty. Such situations may lead practitioners to withdraw from representation in applications in which they today would not. [46]

The ABA rule, like Rule 56, posits that in ex parte proceedings a counsel's duty, beyond avoidance of outright lies, does not begin and end with what would win or lose the matter. The predecessor Model Code contained no similar provision for ex parte proceedings. The general view has evolved to match current Rule 56. One factor that influenced the PTO in 1992 was whether a but-for standard would lead courts to "become increasingly less confident of the Office's product if they get the impression that practitioners and inventors can routinely withhold information from the Office, or … can make up *their own minds* about what is patentable."[47] The Office may feel this factor can weigh less heavily today in view of *Therasense* and of the Supreme Court's endorsement of the clear and convincing evidence standard.[48] But the factor could influence decisions all the more heavily in states where counsel in ex parte proceedings have greater duties of disclosure than the patent bar would in patent prosecution.

If the Office believes its ethics regime should take account of *Therasense*, it can do so without abandoning the ABA Model Rule approach to materiality in ex parte proceedings. The Office's ethics enforcement could distinguish between but-for materiality and other forms of material omissions without declaring omissions that are currently material no longer material. It could, for instance, in disciplinary cases, absent aggravating circumstances such as repeat violations, subject less-than-dispositive omissions to lighter sanctions. Again, in the area of practitioner ethics, the Office has flexibility that the Federal Circuit in *Therasense* regarded as absent in its application of inequitable conduct. If the Office nonetheless adjusts its Rule 56 standard to *Therasense*, it should give practitioners further guidance on how, in that light, to understand their ethical responsibilities.

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[46] The AIA may increase these dilemmas. The Office advances the position in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.,* No. 16-1284 (Fed. Cir.), that the AIA changed the law on secret sales. *See* MPEP ¶ 2152.02(d). If successful, this view will give rise to close cases on whether transactions a client sees as confidential should be held to have made an invention publicly available.

[47] 57 Fed. Reg. at 2024 (emphasis in original.)

[48] *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91 (2011).

5. Conclusion

It need not be seen as intrinsically desirable for the USPTO to conform its duty of disclosure's materiality standard to the *Therasense* inequitable conduct standard. Other options are available to the Office that might better serve quality examination and ethical practice. Indeed, the Federal Circuit may take different approaches to inequitable conduct in view of the AIA. I hope these comments will contribute to the USPTO's articulating a fully considered rationale for its next step, whatever route it takes.

Respectfully submitted,

/s/

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