Disclosure in Prosecution and Litigation

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1. **During Prosecution**

A. **General Ethical Obligations Including “Rule 11” Type Obligations**

During prosecution and all Office proceedings, practitioners have general obligations that may require investigation before filing a paper in the Office. For example:

- “A practitioner shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good-faith argument for an extension, modification or reversal of existing law.” 37 C.F.R. § 11.301.
- A practitioner shall not knowingly...[m]ake a false statement of fact or law to a tribunal or fail to correct a false statement of material fact or law previously made to the tribunal by the practitioner...” 37 C.F.R. § 11.303(a)(1).
- “A practitioner shall not knowingly...[o]ffer evidence that the practitioner knows to be false. If a practitioner, the practitioner’s client, or a witness called by the practitioner, has offered material evidence and the practitioner comes to know of its falsity, the practitioner shall take reasonable remedial measures, including, if necessary, disclosure to the tribunal. A practitioner may refuse to offer evidence that the practitioner reasonably believes is false.” 37 C.F.R. § 11.303(a)(3).
- “A practitioner who represents a client in a proceeding before a tribunal and who knows that a person intends to engage, is engaging or has engaged in criminal or fraudulent conduct related to the proceeding shall take reasonable remedial measures, including, if necessary, disclosure to the tribunal.” 37 C.F.R. § 11.303(b).

B. **Candor-Specific Obligations: Rule 56**

“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.” 37 C.F.R. § 1.56.

1. **Who**

Subsection(c) of Rule 56 defines who is under an obligation of candor. It defines “individuals associated with the filing or prosecution of a patent application” to include only:

(1) Each inventor named in the application;
(2) Each attorney or agent who prepares or prosecutes the application; and
(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

37 C.F.R. § 1.56(c).

2. What

Subsection (b) of Rule 56 requires that a person substantively involved in prosecution must disclose information that either (a) establishes a prima facie case of unpatentability of a claim or is inconsistent with a position taken before the USPTO with respect to patentability of a claim. 37 C.F.R. § 1.56(b).

2. During Post-Grant Proceedings.

A. General Obligations

In addition to the general ethical obligations discussed above, any filing in IPR, signature of practitioner certifies, based on reasonable investigation, that:

1. statements made on own knowledge are true and statements made on information and belief are believed to be true;
2. allegations/factual contentions have evidentiary support;
3. legal contentions are warranted by existing law or a nonfrivolous argument to change existing law or establish new law; and
4. no improper purpose.

See 37 C.F.R. § 42.118.

B. Candor-Specific Obligations: Unamended Claims

There are two distinct rules. One is a general duty of candor: “Parties and individuals involved in the proceeding have a duty of candor and good faith to the Office during the course of a proceeding.” 37 C.F.R. § 42.11.

The second is narrower. It provides: “Unless previously served, a party must serve relevant information that is inconsistent with a position advanced by the party during the
proceeding concurrent with the filing of the documents or things that contains the inconsistency.” 37 CFR § 42.51.

C. **Candor-Specific Obligations: Proposed Substitute Claims**


3. **Unenforceability of Issued Patents: Therasense.**

Inequitable conduct is an equitable defense disfavored by the Federal Circuit in part because of its historical abuse and its potential for disproportionate consequences even when unproven. For instance, the Federal Circuit has expressed concern regarding “the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive…” *Northern Telecom, Inc. v. Datapoint*, 908 F.2d 931, 939 (Fed. Cir. 1990). This ease had caused inequitable conduct to become a “common litigation tactic,” “overplayed,” and an “absolute plague” that was “cluttering up the patent system.” *Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc). Further, the Federal Circuit has recognized that allegations of inequitable conduct can have “ruinous consequences for the reputation of [a] patent attorney.” *Id.*, at 1288–89. The routine nature of the inequitable conduct charge and the potential consequences led to a “deluge” of over-disclosure. “Applicants disclose too much prior art for the PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct.” *Id.*, at 1289.

Accordingly, the Federal Circuit sharply restricted the scope of inequitable conduct in *Therasense*. Under *Therasense*, a charge of inequitable conduct based on the withholding of
information from the USPTO requires clear and convincing evidence that: (1) the withheld information was material; (2) a person substantively involved in the prosecution (or, presumably, a post-grant proceeding); knew the withheld information was material; and (3) that person specifically intended to deceive the USPTO by withholding the information. *Therasense*, 649 F.3d at 1290. The prongs of materiality and intent are considered separately. *Id.* They are not to be viewed on a “sliding scale” where weak evidence of one is bolstered if the evidence of the other requirement is strong. *Id.* Thus, a showing of materiality does not equate to intent. *Id.* (“Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.”). (A rare exception for “affirmative egregious misconduct” exists but is beyond the scope of this paper.)

Finally, even if all three conditions are met – clear and convincing evidence that a person substantively involved in prosecution knew of information, knew it had been material, and the single most reasonable inference is that the person had withheld it with intent to deceive the USPTO – a federal judge must still engage in a balancing of equities to determine if the conduct before the USPTO was so egregious as to warrant holding the entire patent unenforceable. *Id.* at 1287 (“If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant's conduct before the [US]PTO warrants rendering the entire patent unenforceable.”).

**A. Who.**

Inequitable conduct hinges on the specific knowledge and conduct of an inventor, prosecution attorney, or individual *substantively involved* in prosecution of a patent application. *See Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973, 974, n.1 (Fed. Cir. 2010) (stating that beyond the inventor and the prosecuting attorney or agent, whether an
individual “owed a duty of candor to the PTO, such that his misconduct would be chargeable to [the patent owner], depends on whether he was an individual who was ‘substantively involved in the preparation or prosecution of the application’ and 'associated with the inventor or assignee.’”) (citing 37 C.F.R. § 1.56(c)(3)). The “knowledge” of someone who was not substantively involved or information known to “entities” is of no relevance. See Avid Identification Sys., 603 F.3d at 973, 974, n.1 (noting that “only individuals, rather than corporations . . . owe a duty of candor to the PTO).

And it is not every individual: only those “substantively involved” in prosecution. Substantive “involvement relates to the content of the application or decisions related thereto, and that the involvement is not wholly administrative or secretarial in nature.” Therasense at 974; see id. at 973–74, n.1 (stating that beyond the inventor and the prosecuting attorney or agent, whether an individual “owed a duty of candor to the PTO, such that his misconduct would be chargeable to [the patent owner], depends on whether he was an individual who was ‘substantively involved in the preparation or prosecution of the application' and 'associated with the inventor or assignee.’”)

B. What.

Information is material under Therasense only where “the [US]PTO would not have allowed a claim had it been aware of the undisclosed prior art.” Id. at 1291. This is known as “but-for” materiality, because it requires that the claim would not have issued but for the failure to disclose. See Therasense, 649 F.3d at 1290. In assessing whether the USPTO would have rejected a claim had it known of the undisclosed information, the Court applies the preponderant standard and gives a claim its broadest reasonable interpretation. Id. at 1291-92; Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1334 (Fed. Cir. 2012).
The materiality required for inequitable conduct is much narrower than the materiality standard during patent prosecution in 37 C.F.R. § 1.56(b). Therasense, 649 F.3d at 1293 (“This court does not adopt the definition of materiality in PTO Rule 56.”) The Federal Circuit specifically “decline[d] to adopt the current version of Rule 56 in defining inequitable conduct because reliance on this standard has resulted in the very problems this court sought to address by taking [the Therasense] case en banc.” Id. at 1289-90, 1294. Thus, whether information should have been disclosed to the USPTO during prosecution under the Rule 56 standard is not determinative of the statutory equitable defense of inequitable conduct. See Therasense, 649 F.3d at 1294–95 (“This court declines to adopt the current version of Rule 56 in defining inequitable conduct because reliance on this standard has resulted in the very problems this court sought to address by taking this case en banc”).

C. Knowledge During Pendency of a Claim the Information was Material to It.

Under Therasense, even clear and convincing proof that a person substantively involved in prosecution knew of material information is not enough: in addition, there must be clear and convincing evidence that that person also “knew that it was material…” Therasense 649 F.3d 1290. Thus, there must be proof that while a claim was before the Office, a person substantively involved knew that disclosure of the information more likely than not would have resulted in a rejection by the USPTO of that claim, if given its broadest reasonable interpretation.

D. Intent to Deceive

Where clear and convincing evidence demonstrates that an individual substantively involved in a case not only knew of material information and knew that it was material, but that that person “made a deliberate decision to withhold it.” Therasense 649 F.3d 1290. This is a high hurdle: a person’s “specific intent to deceive must be ‘the single most reasonable inference able
to be drawn from the evidence.’” *Id.* (citations omitted). The facts must “require a finding of deceitful intent in the light of all the circumstances.” *Id.* (emphasis in original). Therefore, “when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.* at 1290–91.


Significantly, while the intent of an individual substantively involved in patent prosecution is relevant to an inequitable conduct analysis, during prosecution examiners do not consider intent because “inequitable conduct is not set by statute as a criterion for patentability but rather is a judicial application of the doctrine of unclean hands which is appropriate to be handled by the courts rather than by an administrative body.” *See MPEP § 2010 (7th ed.*) (noting that “Office is not the best forum in which to determine whether there was an ‘intent to mislead’; such intent is
best determined when the trier of facts can observe demeanor of witnesses subjected to cross-examination.

D. Equitable Balancing

Even if all of the other elements are established, a federal judge must still engage in a balancing of equities to determine if the applicant's conduct before the USPTO was so egregious as to warrant holding the entire patent unenforceable. *Id.* at 1287 (“If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable.”).

4. Concluding Thoughts.

A. Because You Would Never Act Unethically, You Must have Known of the Information.

In cases I have seen, “experts” point to the ethical obligations of lawyers to argue that, because prosecution counsel plainly did never act unethically, and so did investigate as required, the practitioner must have known of the information. Of course, this undermines the careful cabining of *Therasense*. At the same time, however, the existence of *Therasense* places practitioners in an awkward place, but one common to many other areas of law: if the practitioner does not “know” of the information, or of its materiality, it need not be disclosed, and so the lawyer should (a) convince herself that he does not know it is material, or (b) even willfully avoid learning of its contents to further that ignorance.

B. The Conflict Between Practitioner and Client and a Comparison to Best Mode.

This gaps between *Therasense* and the ethical disclosure obligations also creates conflicts of interest between the lawyer’s ethical obligations of disclosure and the client’s interests. There
will be no impact on a patent, for example, granted even if the practitioner knows of inconsistent information but does not disclose it.

Congress altered the requirements for disclosing the best mode when it amended Section 112 of the Patent Act. With the newly added language underlined and the deleted language struck through, the pertinent portion of that statute now provides:

The specification shall contain … the best mode contemplated by the inventor of carrying out his invention or joint inventor of carrying out the invention.

Thus, Congress made clear that the best mode known to an inventor or a joint inventor must be included in the specification. In the House Judiciary Committee Report on the America Invents Act, Congress stated that the best mode was a “disclosure required of an applicant” as “part of the important tradeoff that underlies the patent laws: the grant of a limited-term monopoly in exchange for disclosure of the invention.”

Somewhat paradoxically, however, Congress eliminated best mode as a defense to patent validity and enforceability and otherwise eliminated its significance. For example, while before the AIA Section 282 made the failure to comply with any provision of Section 112 a defense to patent infringement, as amended Section 282 now states that “the failure to disclose the best mode shall not be a basis on which an claim of a patent may be canceled or held invalid or otherwise unenforceable….” Similarly, a later filed application can claim priority to an earlier filed one even though the earlier application fails to disclose the best mode for practicing the invention.

This is true with provisional applications as well.

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1 Comm. Rep. 112-98 (June 1, 2011).
2 Id.
4 35 U.S.C. § 120.
Thus, though continuing the requirement in Section 112 that a specification include the best mode known to an inventor, and clarifying that the requirement applied to co-inventors, Congress at the same time severely eliminated the impact of failing to disclose the best mode – but only on issued patents. The USPTO has stated that the requirements to disclose the best mode remain unaffected by the AIA. In its “frequently asked questions” section on the AIA, the USPTO explains:

**Question BM2:** Does AIA’s amendment to 35 U.S.C. 282(a)(3) impact current patent examination practice regarding evaluation of an application for compliance with the best mode requirement of 35 U.S.C. 112?
No. As this change is applicable only in patent validity or infringement proceedings, it does not change current patent examination practices set forth in MPEP § 2165.

**Question BM3:** What is the impact of AIA’s amendment to 35 U.S.C. 282(a)(3) concerning Best Mode?
The failure to disclose the best mode shall no longer be a basis, in patent validity or infringement proceedings, on which any claim of a patent may be canceled or held invalid or otherwise unenforceable. As stated above, this new practice does not affect the patent examination practice.6

The reason for this position, of course, is the plain language of the AIA: the USPTO does not during prosecution make determinations as to validity or enforceability (except in rare circumstances): it addresses patentability.

The strange dichotomy of requiring disclosure of the best mode in the specification but, after issuance, giving the omission no impact leaves practitioners and patent applicants in an odd place: in that sense, it is precisely like a practitioner who knows of inconsistent information that is not but-for material.

C. Document and Advise.

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6 [http://www.uspto.gov/aia_implementation/faq.jsp#heading-2](http://www.uspto.gov/aia_implementation/faq.jsp#heading-2)
Practitioners placed in these gaps, or where materiality is uncertain, should consider documenting the reasons why the practitioner concluded the information was not material or inconsistent. If the OED investigates, or the practitioner’s knowledge becomes an issue in some other way, a contemporaneous, good faith, and reasonable explanation may provide a defense to an OED explanation and a basis to eliminate any charge of inequitable conduct. Informing the client of the benefits and risks of the approach is important as well.

D. USPTO to the Rescue?

The USPTO has twice sought to amend Rule 56 to match Therasene. The latest effort is, it seems, stuck in the “to adopt one rule an agency must repeal two” concept.