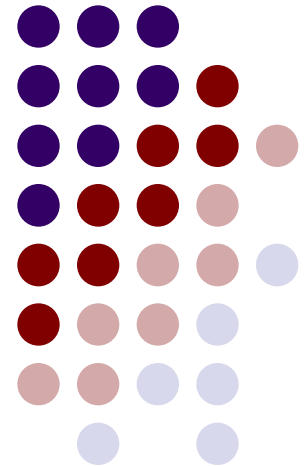


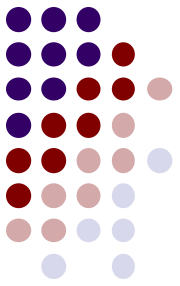


Birch
Stewart
Kolasch
Birch LLP

Proposed Changes to Rules 56(b) and 555(b) – Duty of Disclosure

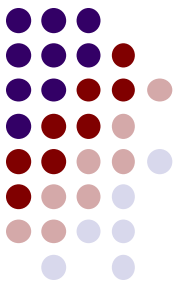
BSKB firm lunch lecture
January 11, 2017
Rick Gallagher





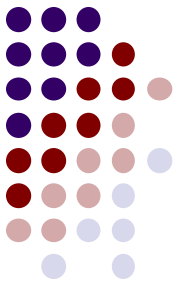
Rules 56(b) and 555(b)

The PTO is proposing revisions to the materiality standard for the duty to disclose information in patent applications and reexamination proceedings.



Rules 56(b) and 555(b)

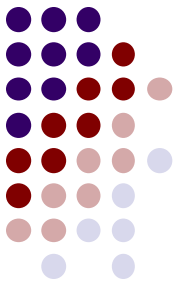
According to a Notice published in the Federal Register (Oct. 29, 2016), the revisions are being proposed “in light of a 2011 decision by the U.S. Court of Appeals for the Federal Circuit The Office previously issued a notice of proposed rulemaking on July 21, 2011, and due to the passage of time since the comment period closed in 2011, the Office considers it appropriate to seek additional comments.”



Rules 56(b) and 555(b)

The proposed amendments to the rules were prompted by the 2011 decision of the Federal Circuit in

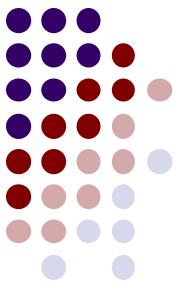
Therasense, Inc. v. Becton, Dickinson & Co.,
649 F.3d 1276 (Fed. Cir. 2011) (*en banc*).



Rules 56(b) and 555(b)

Rule 56 (37 CFR 1.56) is entitled
“Duty to disclose information material to
patentability.”

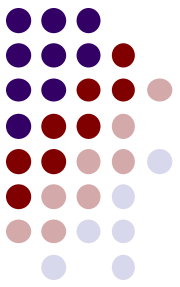
Rule 555 (37 CFR 1.555) is entitled
“Information material to patentability in *ex parte* reexamination and *inter partes* reexamination proceedings.”



Rules 56(b) and 555(b)

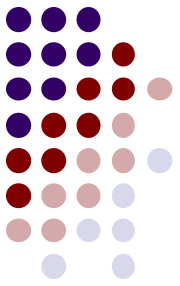
In the proposed rules, 37 CFR 1.56(b) and 1.555(b) are amended to recite the “but-for” materiality standard set forth in *Therasense*.

This presentation looks at the proposed amended versions of 37 CFR 1.56(b) and 1.555(b), and at formal “comments” which have been published with regard to the proposed amended versions of those rules.



Rules 56(b) and 555(b)

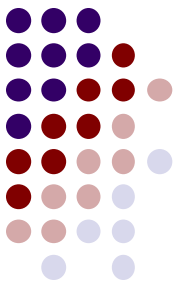
Rule 56(b) currently begins with the following text: “Under this section, information is material to patentability when it is not cumulative to information already of record ... in the application and (1) it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office , or (ii) Asserting an argument of patentability.”



Rules 56(b) and 555(b)

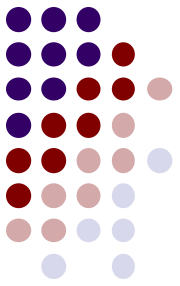
Rule 56(b) then goes on to explain what it means by a *prima facie* case of unpatentability.

Rule 555(b) is virtually identical to Rule 56(b), except that Rule 555(b) refers only to reexamination proceedings.



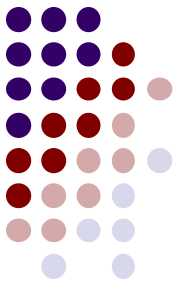
Rules 56(b) and 555(b)

In connection with the amendment of Rule 56(b), Rule 56(a) would be amended in part as follows: “Each individual associated with the filing and prosecution of the 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]] under the but-for materiality standard as defined in paragraph (b) of this section.”



Rules 56(b) and 555(b)

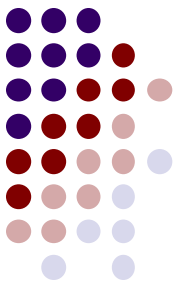
Rule 555(a) would be amended in part as follows: “Each individual associated with the patent owner in a reexamination proceeding has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability in a reexamination proceeding under the but-for materiality standard as defined in paragraph (b) of this section.”



Rules 56(b) and 555(b)

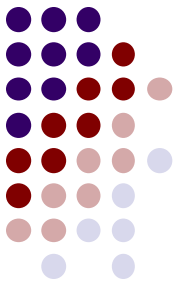
NOTE: the PTO is also proposed to amend Rules 56(a) and 555(a) to explicitly incorporate affirmative egregious misconduct (*e.g.*, knowingly providing incorrect information in Declarations, *etc.*) as satisfying the materiality prong of inequitable conduct.

However, this presentation is focused on the proposed changes to the materiality standard in Rules 56(b) and 555(b).



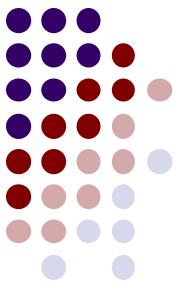
Rules 56(b) and 555(b)

As noted previously, Rules 56(b) and 555(b) are currently similar to one another. Both are currently fairly lengthy, and refer to information being material to patentability, and to the information establishing (by itself or in a combination) a *prima facie* case of obviousness, and to information refuting or being inconsistent with a position taken in arguments in the PTO.



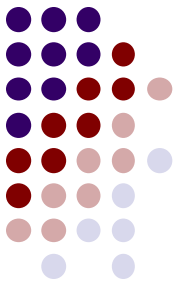
Rules 56(b) and 555(b)

Rule 56(b) would be amended to recite in its entirety: “Information is but-for material to patentability if the Office would not allow a claim if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.”



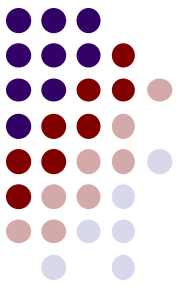
Rules 56(b) and 555(b)

Rule 555(b) would be amended to recite in its entirety: “Information is but-for material to patentability if, for any matter proper for consideration in reexamination, the Office would not find a claim patentable if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.”



Background

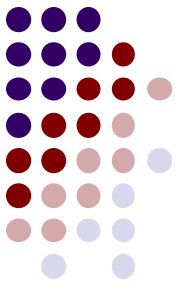
In its discussion of the background for the proposed rule changes, the PTO stated that “The Federal Circuit tightened the materiality standard to ‘reduce the number of inequitable conduct cases before the courts and ... cure the problem of overdisclosure of marginally relevant prior art to the PTO.’ *Therasense*, 649 F.3d at 1291.”



Background

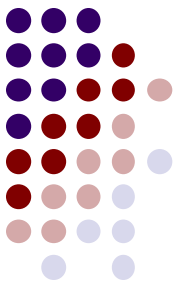
The PTO goes on to say that the Federal Circuit held in *Therasense* that the materiality required to establish inequitable conduct in the context of withheld references is “but-for” materiality.

The PTO noted that the Federal Circuit said that “in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”



Background

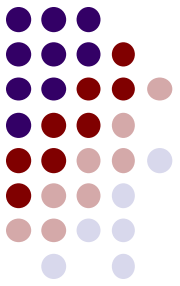
In the Notice of proposed rulemaking, the PTO asserts that its proposal to explicitly mention “but-for” materiality in Rules 56(b) and 555(b) “would avoid divergence between the Office’s materiality standard for the duty of disclosure and the but-for inequitable conduct materiality standard set forth in *Therasense*.”



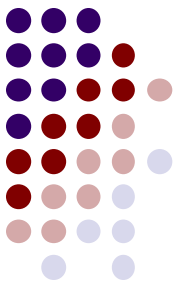
Background

The PTO declared that “A unitary materiality standard is simpler for the patent system as a whole. Under the single but-for standard of materiality, patent applicants will not be put in the position of having to meet one standard of materiality ... in defending against inequitable conduct allegations and a second, different materiality standard when complying with the duty of disclosure before the Office.”

Background

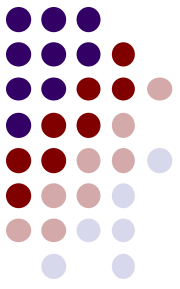


In response to a comment on the previous proposed changes to the Rules, the PTO made it clear that “... under the standard in this currently proposed rule, an applicant would be under no duty to provide information from related applications unless that information is but-for material.”



Background

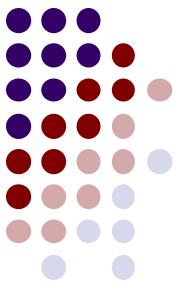
Regarding proposed Rule 555(b), the PTO background discussion in the Notice indicated that “this currently proposed rule encompasses disclosure of information as to any matter that is appropriate for consideration in a reexamination proceeding (e.g., admissions by patent owner), as opposed to being limited to patents and printed publications.”



Background

To summarize, since the current language of Rules 56(b) and 555(b) refers to *prima facie* unpatentability rather than to “but-for” materiality, the PTO had proposed rule changes, based upon the *Therasense* decision, on July 21, 2011.

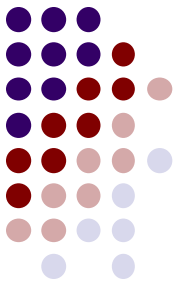
Those former proposed rule changes were never adopted.



Background

The PTO has now revised the proposed rule changes to be the changes noted earlier in this presentation, based upon (i) written comments on the former proposed rule changes, (ii) subsequent relevant Federal Circuit decisions, and (iii) the America Invents Act having been implemented.

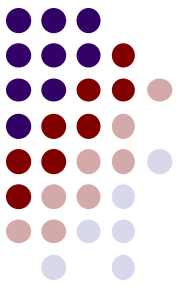
The comment period on the currently proposed rule changes expired on December 27, 2016.



BIO comments

The Biotechnology Innovation Organization, an organization comprising biotechnology companies, academic institutions, and other entities in the U.S. and foreign countries, filed comments on the current proposed rule changes.

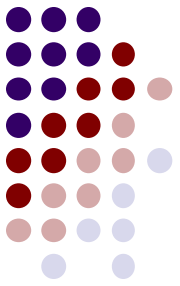
BIO's comments provide a good overview of the implications of the proposed rule changes.



BIO comments

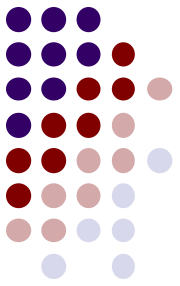
BIO's position is that the PTO's proposal to import the judicial materiality standard into its Rules 56 and 555 would not contribute to greater stability in the law, or to legal certainty, or to meaningful changes in applicant disclosure practices. BIO's position appears to be that Rule 56 is unnecessary and should be revoked.

The following slides reproduce each of BIO's detailed comments.



BIO comments

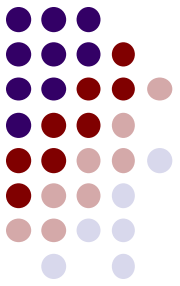
The proposed revisions do not contribute to greater stability in the law: “The USPTO proposes to import the judicial materiality standard into its Rule 56. There is good reason to believe, however, that the *Therasense* standard, in the course of judicial interpretation, will be subject to drift in the courts over time.



BIO comments

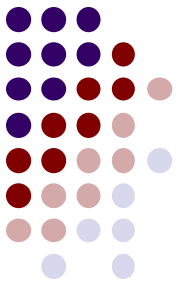
By adopting the judicial standard the USPTO would allow the evolution of its own administrative disclosure standards to be driven entirely by private litigation to which the USPTO is not a party, and where self-interested litigants are expected to argue over proper prosecution conduct without the USPTO's institutional interests in mind.

BIO comments



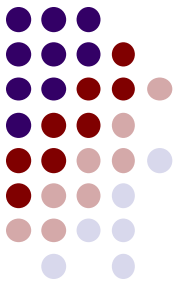
It is only a matter of time until a post-*Therasense* court decides a question of ‘whether the USPTO would not have allowed a claim’ in a way with which the USPTO might, perhaps, disagree. ...

BIO comments



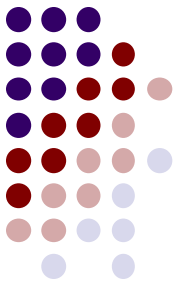
In short, most BIO members do not expect that administrative adoption of a judicial standard that is sure to evolve – and possibly erode – over time is the approach that will most benefit the USPTO and the applicant community.”

BIO comments



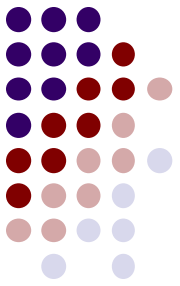
The proposed revisions do not contribute to greater legal certainty: “The USPTO’s proposed revised Rule 56 does not create significantly greater legal certainty about the prior art applicants would need to submit. Under current Rule 56, applicants need to submit information that would be sufficient for a *prima facie* case of invalidity.

BIO comments

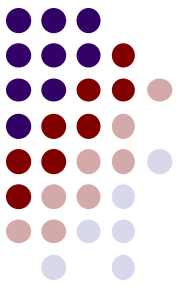


If the *Therasense* standard were adopted by regulation, applicants would need to submit ‘but-for’ material information – i.e., information that would be sufficient to maintain a rejection and make it final. The ‘delta’ between the two standards is not clear, and possibly not very large.

BIO comments

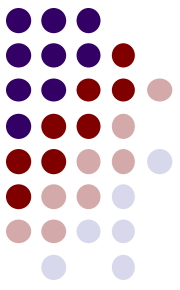


For the most part, applicants likely will not be able to predict the sufficiency of references for a final determination of unpatentability with significantly greater certainty than they can predict the sufficiency of the same references for a *prima facie* case. ... the proposed adoption of the *Therasense* materiality standard is thus not very helpful as a guide for applicants in deciding which art to disclose.”



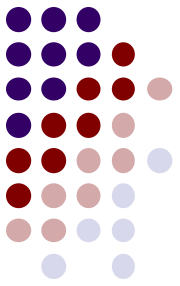
BIO comments

The proposed revisions are unlikely to cause significant changes in applicant disclosure practices: “BIO members believe the USPTO’s proposed rule may accomplish less than the Office might hope. For the reasons stated above, it is unlikely applicants would feel comfortable disclosing less art to the USPTO*, unless the Office provides applicants additional safeguards that are not provided in the Proposed Rule.



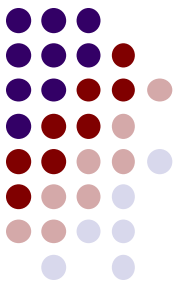
BIO comments

* BIO member also have observed that the practice of over-disclosing information is unlikely to change by adoption of the *Therasense* materiality standard because making a decision to withhold information, even under *Therasense*, continues to create an increased risk in view of the inequitable conduct's 'intent prong' relative to the significant risk reduction caused by disclosing information. In other words, there is little downside to disclosing more, rather than less.



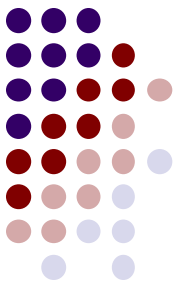
BIO comments

The advent of *inter partes* review proceedings in particular has created powerful incentives to make voluminous prior art submissions during prosecution, in the hope of later benefiting from whatever little presumption of validity the PTAB might be willing to afford the patent.



BIO comments

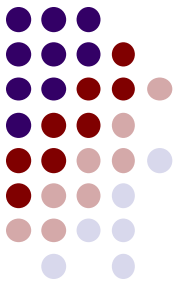
With respect to non-prior art ‘affirmative’ disclosure, e.g., responses to foreign office actions or arguments in related cases (‘inconsistent positions’), adoption of the *Therasense* standard may provide at least some relief, as such disclosures would be measured under a higher ‘egregiousness’ standard. However, even for these affirmative non-prior art disclosures, applicants may be hesitant to alter their disclosure practices until the new and uncertain egregiousness standard is better developed in the law.”



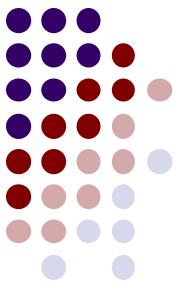
BIO comments

The continued need for a regulatory duty of disclosure is unclear: “The USPTO has not provided a clear explanation of why it continues to need Rule 56. If the PTO wants only the *Therasense* standard, then there would seem to be no need for the rule – it is already the law. If the intention is to prevent fraud, lying, falsification, perjury and the like, federal statutes such as Section 1001 of Title 18 of the U.S. Code provide the applicable standard and the appropriate reach. The USPTO should affirm that it seeks nothing more.

BIO comments

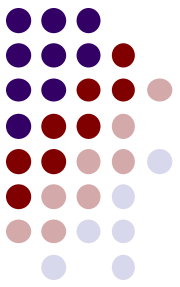


In addition, Rule 56 is enforceable only against registered practitioners anyway; notably, practitioners are bound by ethical canons and standards of professional conduct and could surely be sanctioned for serious misconduct even if no Rule 56 existed. Moreover, the America Invents Act expanded the USPTO's authority to sanction practitioner misconduct.



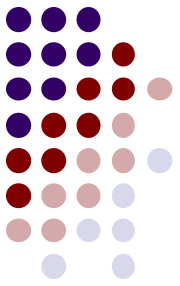
BIO comments

It is thus not clear why Rule 56 continues to be necessary at all. If, as stated in the propose rule, the USPTO’s intent is to encourage the submission and discussion of only the most relevant prior art and to facilitate examiner-applicant interactions, the proposed rule falls short.”



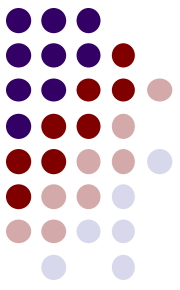
BIO comments

The America Invents Act has changed the picture: The America Invents Act has surely reduced the need for Rule 56, and any modification to Rule 56 should take into consideration these significant reforms. The Act established new post-grant and *inter partes* review proceedings, expanded the Director's reexamination authority, and provided increased opportunities for third-party submission of prior art and patentee representations about claim scope, amongst other provisions that enhance transparency and public participation in the patent examination and review process.



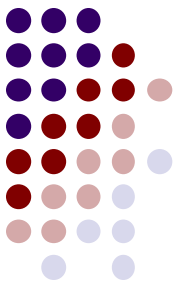
BIO comments

These new provisions provide strong and effective checks on instances of nondisclosure and misrepresentation during patent prosecution. The need to address nondisclosure of information through regulation, in particular in relation to information that is publically available and readily obtainable by the USPTO, now seems much diminished. Moreover, the USPTO must balance the benefits of maintaining a rule that punishes nondisclosure and misrepresentation against the inevitable result of over-disclosure and ‘no comment’ prosecution.



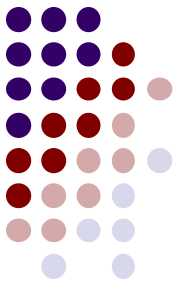
BIO comments

Ironically, alarmingly high institution and invalidation rates in the new AIA PTAB trial proceedings have created their own powerful incentives for applicants to ‘bulk up’ their prosecution histories with additional prior art references. Today, no rational applicant would want to rob itself of at least the opportunity to later argue to the PTAB that references presented in an IPR petition were originally presented and considered by the examiner. Thus to the extent the Federal Circuit’s post-*Therasense* inequitable conduct jurisprudence has reduced the need for overdisclosure during prosecution, the PTA’s application of 35 U.S.C. § 325(d) has taken up the slack.”



Rules 56(b) and 555(b)

The mention of § 325(d) in BIO's last comment refers to *Inter Partes* Review practice, where an opposing party presumably cannot argue that it did not know of a prior art reference (and so file for a 2nd or subsequent IPR) if the reference is listed on the face of the patent – which encourages listing as many patents as possible on the face of the patent.

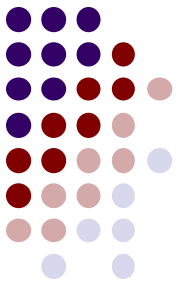


Rules 56(b) and 555(b)

CONCLUSION:

It remains to be seen how, if at all, the PTO will revise 37 CFR 1.56(b) and 37 CFR 1.555(b).

Rules 56(b) and 555(b)



the end