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New Supplemental Examination: USPTO Outlines New Rules

Navigating the New Mechanism to Cure Inequitable Conduct

TUESDAY, FEBRUARY 14, 2012

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Scott A. McKeown, Partner, **Oblon Spivak McClelland Maier & Neustadt**, Alexandria, Va.

Lisa A. Dolak, Angela S. Cooney Professor of Law, **Syracuse University College of Law**, Syracuse, N.Y.

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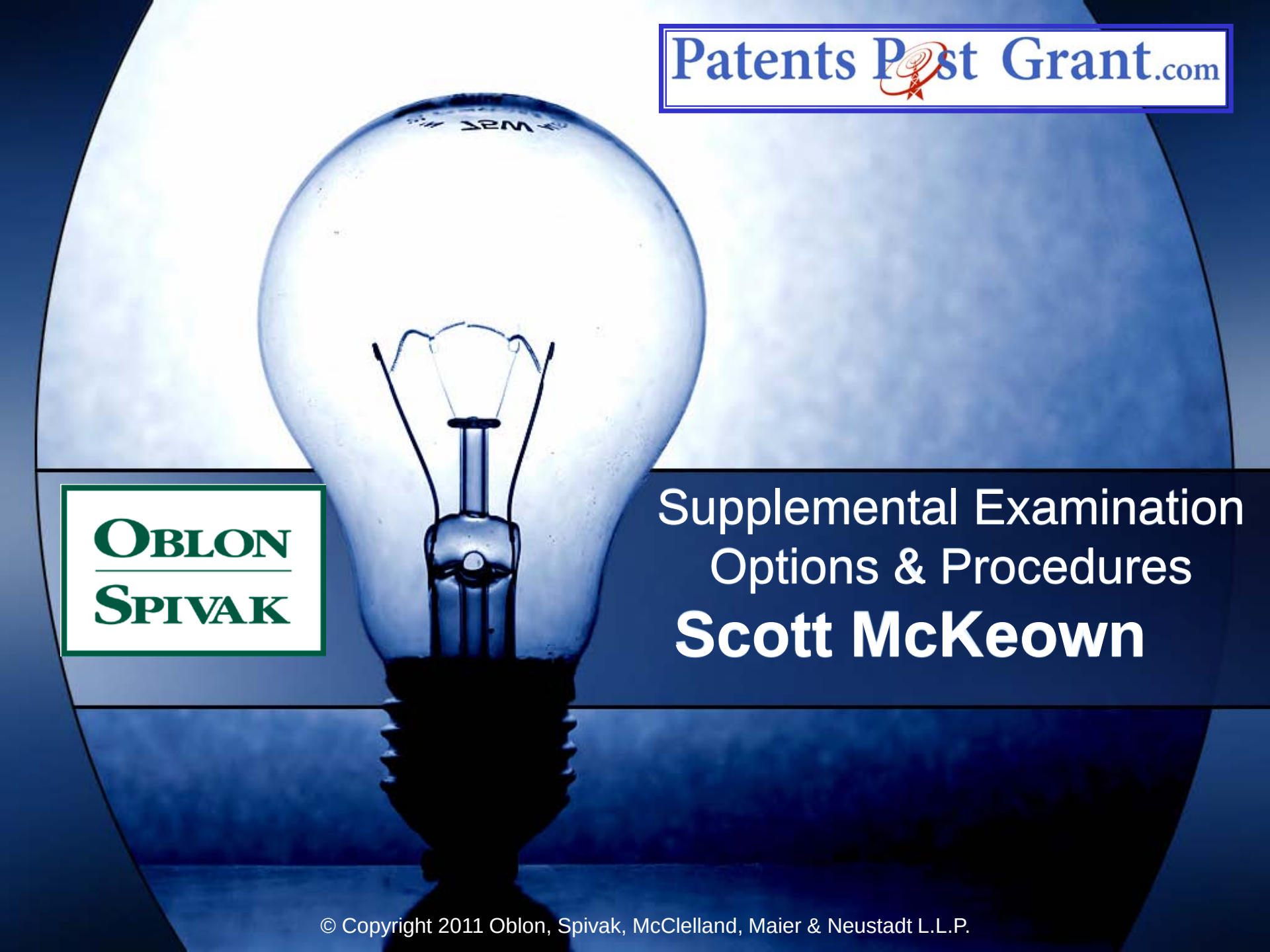

Evolution & Reform

- **America Invents Act Signed into Law 9/16/11**
  - Key Deadlines, 9/16/11, 9/16/12 & 3/16/13
- **What's Missing?**
- **What Works?**
- **What Doesn't?**
- **Patent Reform History & CAFC**
  - Therasense to the Rescue!

Which Patentee Fix?

Spectrum of PO Fixes:

- **Continuations/Divisionals?**
  - Best practice
- **Certificate of Correction (typos, inventor names, etc).**
  - Minor in character 35 USC § 255 (prospective)
    - Otherwise certificate is invalid (no intervening rights)
  - Judicial correction (retroactive)
- **Ex Parte Patent Reexamination (owner)**
- **Patent Reissue**
- **Supplemental Examination (9/16/12)?**

Supplemental Examination Statute

- 35 USC § 257 Supplemental examinations to consider, reconsider, or correct information
- (a) REQUEST FOR SUPPLEMENTAL EXAMINATION.—A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct **information** believed to be relevant to the patent, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.
- (b) REEXAMINATION ORDERED.—If the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised by 1 or more items of information in the request, the Director shall order reexamination of the patent. . . . .

Supplemental Examination Statute

- (c) EFFECT.—
  (1) IN GENERAL.—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**. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.

Supplemental Examination Statute

- (2) EXCEPTIONS.—
- Good Citizen
  (A) PRIOR ALLEGATIONS.—Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)), before the date of a supplemental examination request under subsection (a) to consider, reconsider, or correct information forming the basis for the allegation.

- No Pocket Filings
- (B) PATENT ENFORCEMENT ACTIONS.—In an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)), or section 281 of this title, paragraph (1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.

Proposed Rules 77 FR 3666 (January 25, 2012)

- The fee for a Request for Supplemental Examination ($5,180)
- The fee for a Request for Ex Parte Reexamination issued pursuant to a Request for Supplemental Examination (which will be refunded if reexamination is not ordered) ($16,120) ….$21K total!!
- Any document size fees ($170 for each document between 21 and 50 sheets in length; $280 for each additional 50 pages or fraction thereof)
- An identification of the patent at issue
- A list identifying any other prior or concurrent post-grant USPTO proceedings involving the patent at issue
- An identification of each aspect of the patent to be examined (e.g., claims, specification, drawings, abstract (?), priority claim)

Supp. Ex. Proposed Rules

- A list and copy of each item of information on which supplemental examination is requested (although copies of U.S. patents and published U.S. patent applications do not have to be provided)
- A summary of each item of information that is over 50 pages long—the proposed rules invoke the page size, font size and margin limitations of 37 CFR § 1.52 to prevent patentees from circumventing this requirement by selecting a smaller font size or submitting reduced images of published documents!
- An identification of each issue raised by each item of information
- A separate, detailed explanation for each identified issue, including an explanation of how each item of information is relevant to each aspect of the patent to be examined and of how each item of information raises each identified issue
- A Request may not include any proposed amendments
- The proposed rules prohibit interviews during the Request stage

Supp. Ex. Proposed Rules Request

- A list and copy of each item of information on which supplemental examination is requested (although copies of U.S. patents and published U.S. patent applications do not have to be provided)
- A Request for Supplemental Examination must be filed by all patent owners.
- Although a similar requirement pertains to reissue applications (37 CFR § 1.172), no such requirement pertains to requests for ex parte reexamination. On the one hand, the requirement conforms to the statutory language ("A patent owner may . . .), but stakeholders should consider whether the USPTO should permit fewer than all patent owners to request Supplemental Examination if, for example, a co-owner refuses to cooperate or cannot be found.
- The fees associated with a Request for Supplemental Examination are not reduced for Small Entities.
  (According to the commentary in the Federal Register Notice, the proposed fees are promulgated under 35 USC § 1.41(d)(2), which does not permit the USPTO to offer reduced fees for small entities.)

Supp. Ex. Proposed Rules Request

- Each Request for Supplemental Examination can be based on a maximum of ten "items of information." If a patentee wants to submit a Request for Supplemental Examination based on more than ten items of information, the patentee can file multiple Requests. This rule (and others) appears to be designed to ensure that the USPTO can meet its statutory obligation to make a decision on a Request within three months. However, it will take at least as much effort for the USPTO to review multiple Requests related to the same patent than it will take to review one larger Request. It would be more efficient for the USPTO to permit a single Request to be based on an unlimited number of items of information, even if the USPTO charges additional fee(s) for larger Requests.
- While the proposed rules appear to contemplate serial Requests related to the same patent (noting that a Request can be filed "at any time"), patent holders will want to file Requests promptly in order to be entitled to the benefits of new 35 USC § 257(c).

Supp. Ex. Proposed Rules Request Content

- While the proposed rules appear to contemplate serial Requests related to the same patent (noting that a Request can be filed "at any time"), patent holders will want to file Requests promptly in order to be entitled to the benefits of new 35 USC § 257(c).
- Although "court documents" and "non-patent literature" may be redacted, it appears that "patents, patent application publications, and third-party-generated affidavits or declarations" may not be. It is not clear why the USPTO would draw a distinction between non-patent literature and patents/patent application publications. Patent documents may have lengthy disclosures, only part of which may be relevant to a Request. For example, a patent document may include hundreds of pages of a Sequence Listing or tables of chemical formulas, where only one (or none) are relevant to the issues raised in the Request. Stakeholders should consider whether the USPTO should permit the patent holder to redact any publically available documents, such that only the relevant portions are provided with the Request, particularly in view of the new document size fees!

Supp. Ex. Proposed Rules

- The rules require patent holders to submit documents and items of information that are readily accessible to the USPTO. Although the proposed rules provide that the patent holder does not have to submit copies of U.S. patents and published U.S. patent applications that are cited as items of information, they do require the patent holder to submit a copy of the patent at issue and any post-grant certificates (e.g., certificates of correction and/or reexamination certificates). It is frustrating that the USPTO continues to ignore the wastefulness of requiring the submission of documents that already are in its possession.
- The proposed rules also require patent holders to advise the USPTO of any prior or concurrent USPTO proceedings involving the patent (e.g., reissue, ex parte reexamination, inter partes review or post-grant review proceedings), and to update the USPTO as to any new proceedings "as soon as possible upon the discovery [there]of."
- If the USPTO cannot articulate a need for the patent holder to provide information that the USPTO already has in its possession, these requirements should be removed from the proposed rules.

Supp. Ex. Proposed Rules

- The USPTO will not assign a filing date to a Request unless and until all requirements for a complete Request are satisfied. This rule is consistent with how the USPTO treats requests for reexamination, and ensures that the USPTO has a complete Request on file before its three-month review period begins. However, this rule could jeopardize a patent holder's ability to invoke the protections of 35 USC § 257(c)(1) if an allegation of unenforceability is made after an initial, incomplete Request is filed but before the filing of a complete Request meriting a filing date.

Supp. Ex. Proposed Rules

- **The Decision (CRU)**
- Within three months following the filing date of a Request, the USPTO will determine whether a "substantial new question of patentability" affecting any patent claim has been raised, and will electronically issue a decision that reflects its determination. The USPTO will find a "substantial new question of patentability" if "there is a substantial likelihood that a reasonable examiner would consider the item of information important in determining patentability" as provided in current MPEP § 2242.
- The precise language of the proposed rule states:
- Within three months following the filing date of a request for supplemental examination, the Office will determine whether a substantial new question of patentability affecting any claim of the patent is raised by any of the items of information presented in the request. The determination will generally be limited to a review of the issues identified in the request as applied to the identified aspects of the patent. The determination will be based on the claims in effect at the time of the determination and will become a part of the official record of the patent.

Supp. Ex. Proposed Rules

- The Reexamination Proceeding
- The proposed rules provide that any reexamination ordered pursuant to a Request for Supplemental Examination will be conducted pursuant to 37 CFR §§ 1.530 – 1.570, with exceptions that appear to mirror those in the statute. Additionally, the proposed rules provide that the duty of disclosure during such a reexamination proceeding will be that set forth in 37 CFR § 1.56 (not 37 CFR § 1.555(b)), because the proceeding will be broader in scope than an ex parte reexamination proceeding. Let's hope the USPTO revises 37 CFR § 1.56 to reflect the Federal Circuit's May 2011 decision in Therasense before these new rules take effect!
- Interviews and amendments in reexamination phase
- No PO statement
- Not limited to patents and printed pubs
- 112 and 101?
- IDS FILINGS?????
- Is this really a good deal?

Ethical Considerations Supp. Exam

Professor Dolak

Supplemental Examination: Ethics-Related Considerations

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Ethics-Related Considerations

- Relevant USPTO ethics/candor rules
- AIA impacts
- Ethics implications of SE proposed rules
- Inequitable conduct-related implications
- New disciplinary statute of limitations
- Potential conflict-of-interest issues

USPTO Rules: Candor

- "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 . . .." 37 C.F.R. § 1.56
- Parallel obligation in reexamination 37 C.F.R. § 1.555

Current Materiality Standard (Rules 1.56 and 1.555)

"information is material to patentability when it is not cumulative to information already of record . . ., 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."

Proposed Materiality Standard (July 21, 2011 Fed. Reg.)

"information is material to patentability under *Therasense* if

(1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or

(2) the applicant engages in affirmative egregious misconduct before the Office as to the information"

USPTO Additional Comments

- July 21, 2011 Fed. Reg. Notice:
  - "[E]xpects [change] will reduce the incentive . . . to submit . . . only marginally relevant information"
  - "[I]s considering . . . provid[ing] an incentive for applicants to assist the [USPTO] by explaining/clarifying the relationship of prior art to the claimed invention"
  - "[W]ishes to facilitate and encourage . . . efforts by applicants" "to be forthcoming and submit information beyond that required by proposed Rule 56"

USPTO Rules: Representation

- 37 C.F.R. Part 10:
  - Signature and certification requirements
  - USPTO Code of Professional Responsibility

Signature/Certification

- Rule 10.18 (FRCP 11 counterpart):
  - all documents filed in patent matters must be signed by the filing practitioner (except those requiring applicant signature)
  - “[b]y presenting” (signing, filing, submitting or later advocating), the presenter certifies that . . .

Signature/Certification

- Rule 10.18 certification:
  - "All statements . . . are [or] are believed to be true, and . . . are made with the knowledge that" false statements are punishable as perjury and "may jeopardize the validity or enforceability of any patent . . . resulting therefrom"
  - "To the best of the [presenter's] knowledge, information and belief, formed after an inquiry reasonable under the circumstances, . . ."
    - No improper purpose
    - Legal contentions are warranted by law/nonfrivolous argument
    - Factual contentions have or are likely to have evidentiary support
- Violations are subject to sanctions, including disciplinary action

USPTO Code of Professional Responsibility

- Nine “Canons” (aspirational), plus “Disciplinary Rules” (mandatory)
- USPTO rules:
  - investigation of possible DR violations
  - initiation of, procedures for proceedings to resolve charges
  - imposition of sanctions for violations

USPTO Code

- Thou shalt not, e.g.:
  - “Engage in conduct involving dishonesty, fraud, deceit, or misrepresentation.” (Rule 10.23(b)(4))
  - “Knowingly giv[e] false or misleading information or knowingly participat[e] in a material way in giving false or misleading information, to . . . [t]he Office or any employee of the Office.” (Rule 10.23(c)(2)(ii))
  - “Knowingly violat[e] . . . the requirements of § 1.56 or § 1.555 . . ..” (Rule 10.23(c)(10))

USPTO Code

- Thou shalt:
  - preserve client “confidence[s]” and “secret[s]” (Rule 10.57(b)(1))
  - represent clients zealously (“not intentionally . . . [f]ail to seek the lawful objectives of a client through reasonably available means permitted by law and the Disciplinary Rules”) (Rule 10.84(a)(1))

AIA Impacts

- Creates supplemental examination
- Expressly preserves:
  - Criminal, antitrust and unfair competition liability
  - USPTO's power to
    - Regulate the conduct of those who practice before the Office
    - Investigate and impose sanctions for misconduct
- Revises statute of limitations governing practitioner discipline

Ethics Implications: Supplemental Examination

- Prior information/conduct an owner might seek to correct via SE
  - Referral for “material fraud” investigation?
  - Office of Enrollment and Discipline investigation?
- Conduct during SE
  - Candor, signature/certification, misconduct avoidance obligations apply (as always)
  - Possible new inequitable conduct “opportunities”

SE Proposed Rules: Ethics-Related Issues

- No definition of “material fraud”, but “[t]he Office regards the term . . . to be narrower in scope than inequitable conduct”
- What does *that* mean?
  - Can a material omission qualify?
    - Only when it makes another statement misleading?
    - Only if the patent owner submits a declaration?
    - Yes, because of the (affirmative) duty of candor?

SE Proposed Rules: Ethics-Related Issues

- Will Central Reexamination Unit members be given guidance?
  - e.g., How to handle an SE request reciting facts that reasonably suggest misconduct may have occurred ?
- Will the Office of Enrollment and Discipline pro-actively participate?
  - Whose misconduct (owner or attorney) was it, anyway?
  - Or respond only to complaints against practitioners, referrals from courts?

SE Proposed Rules: Ethics-Related Issues

- Owner must:
  - "explain[] why consideration of the item of information is being requested"
  - "identif[y] each issue raised by each item of information"
  - provide a "separate, detailed explanation for each identified issue"
- Ethics obligations attach; future challengers will scrutinize

Inequitable Conduct-Related Implications (post-SE litigation)

- What information was considered (or reconsidered or corrected) – and what wasn't – in SE?
  - What is the scope of the "immunity"?
- Did the patent owner commit IC in SE?
  - Owner's explanations/disclosures as "but for" material or "affirmative egregious misconduct"

Revised Statute of Limitations

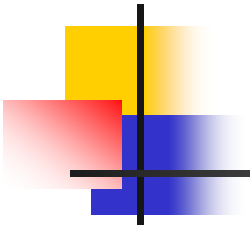
- Prior law: OED required to initiate disciplinary proceedings within five years of asserted misconduct
- AIA: disciplinary proceeding must be commenced no later than the *earlier of*
  - 10 years from the asserted misconduct
  - 1 year "after the date on which the misconduct . . . is made known to an officer or employee of the Office"

Revised Statute of Limitations

- January 5, 2012 Proposed Rules:
  - Describes stages of discipline investigation:
    - Preliminary screening of the allegations
    - Requesting of information from the practitioner
    - Conducting a thorough investigation
    - Submitting the investigated case to the Committee on Discipline for a determination of whether there is probable cause to bring charges against the practitioner
  - One-year statute begins to run “when the OED Director receives the practitioner’s complete, written response to a” request
  - Comment period closes March 5

Potential Conflict Issues

- SE reflects fundamental shift: consequences of candor violations are shifted from the patent owner (impact on property right) to the individual actor
- Owner's and practitioner's interests may diverge:
  - Owner's interest: "cleansing" the patent
  - Practitioner's interest: personal reputation, career, liberty
- (Original) practitioner may need to decline representation
  - Note: that practitioner has no opportunity to participate



Is Supp Exam Worthwhile?

Scott McKeown

Supplemental Examination
Therasense

- *Thereasense* "but for" standard yields options
  - No materiality if patent is confirmed in EXP or Reissue.
- What does Supplemental Examination really offer after *Therasense*?
  - Cure Egregious Conduct (duty of candor)
    - Issues based on duty of Candor? (specific intent)
    - Need to Amend?
    - But is there a practical specter of wrongdoing?
    - **Pendency?**
      - Court uses exact same analysis, so why bother for all but the worst case scenarios? (Judge vs. Examiner)
  - Patent Reissue?

Supplemental Examination
Therasense

Why use Reissue over Supplemental Examination?

- Patent Reissue is slooooooooow
- Try it first....then Walk Away?
- *Tanaka* filings now possible….broaden?
- Reissue could be more attractive if pendency issue addressed
- CHEAPER!!!

Why use EXP over Supplemental Examination?

- Patent Owner Statement (Dec. Evidence, extra bite)
- Special Dispatch?
  - Insulate original claims from 112 and 101 challenges

Patent Reissue

- **Can't Fix Everything!**
  - Recapture
  - Beware *Orita* Doctrine
    - Can't restart divisional practice
  - Terminal Disclaimer Removal?
  - Ex Parte *Shunpei Yamazaki (BPAI 2010-002033)*
- **Think Before You File**
  - All Issued Claims Examined Anew
  - Bilksi/KSR concerns?
  - Other options—prior art problem only?

Patent Reissue

- **251 Patent is Wholly or Partly Inoperative**
  - Oath: Error ~~made without deceptive intent~~
    - At least one
    - Supplemental oaths?...New Rules (January ‘12)
  - Narrowing vs. Broadening (2yrs)
  - Reissue Application for unexpired patents only (reissued for unexpired term)
  - Restart continuation practice
    - Past bias at USPTO (In re Tanaka)
    - Fix problem, then get out (suspend parallel filings)

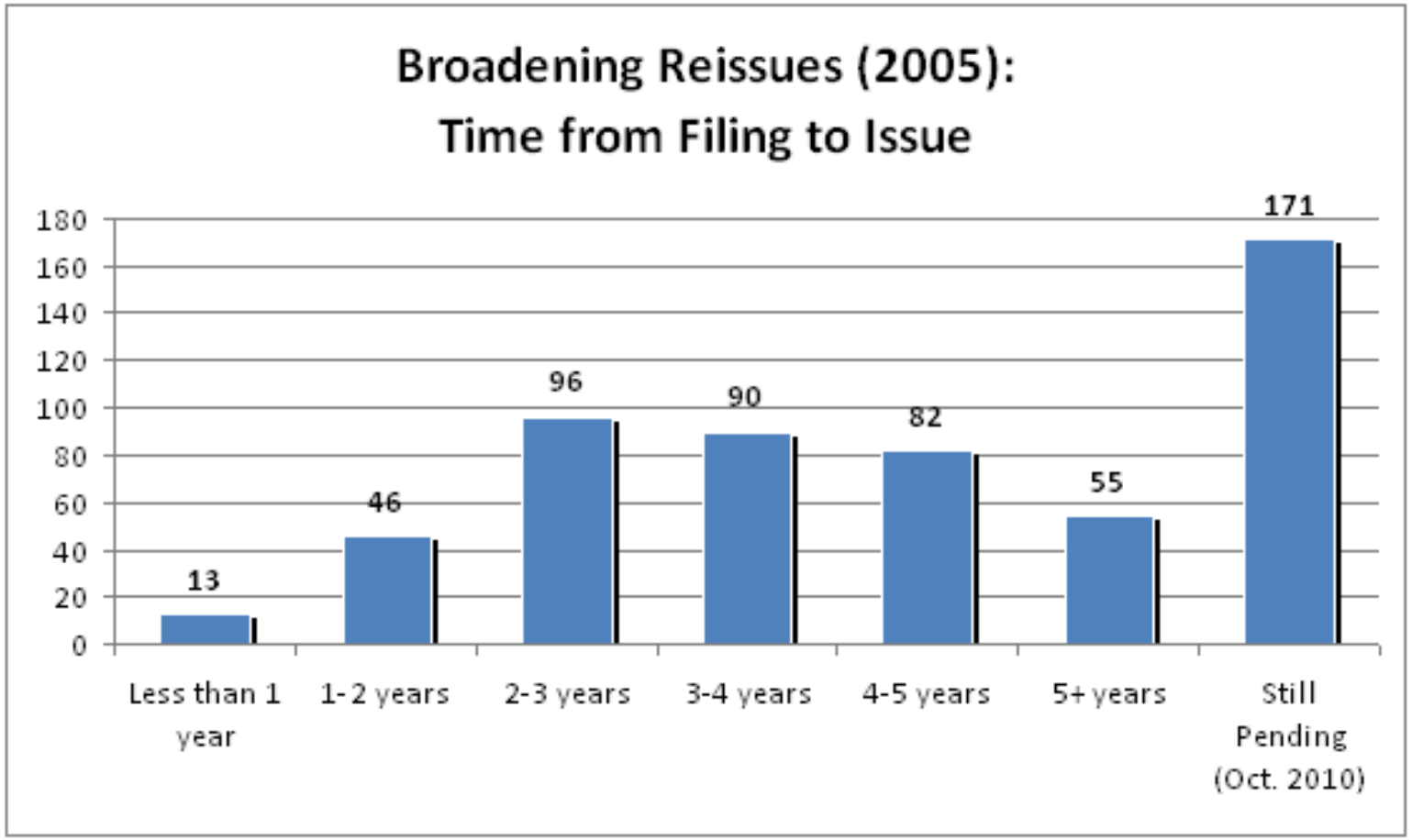
Patent Reexam/Reissue

- **Difference from Ex Parte Patent Reexamination**
  - No SNQ Needed, fix spec, drawing, divided infringement/indirect infringement, etc
  - All claims examined, all statutes
  - New Search
  - Continuation/RCE practice, EOTs
  - Changes up front/intervening rights (252)
  - Lack of Special Dispatch/Dedicated examiners (CRU)
- **Only way to Broaden**

Broadening Reissue

- Within two years of issuance
- Recapture?
  - No prosecution “do over”
- Oath Issues (all inventors)
  - Unequivocal statement
- Inexperienced examiner?
- Continuation Laches? (In re Staats)
- **Pendency?**
  - **50% still pending after 5 years**

Broadening Reissue



753 Total

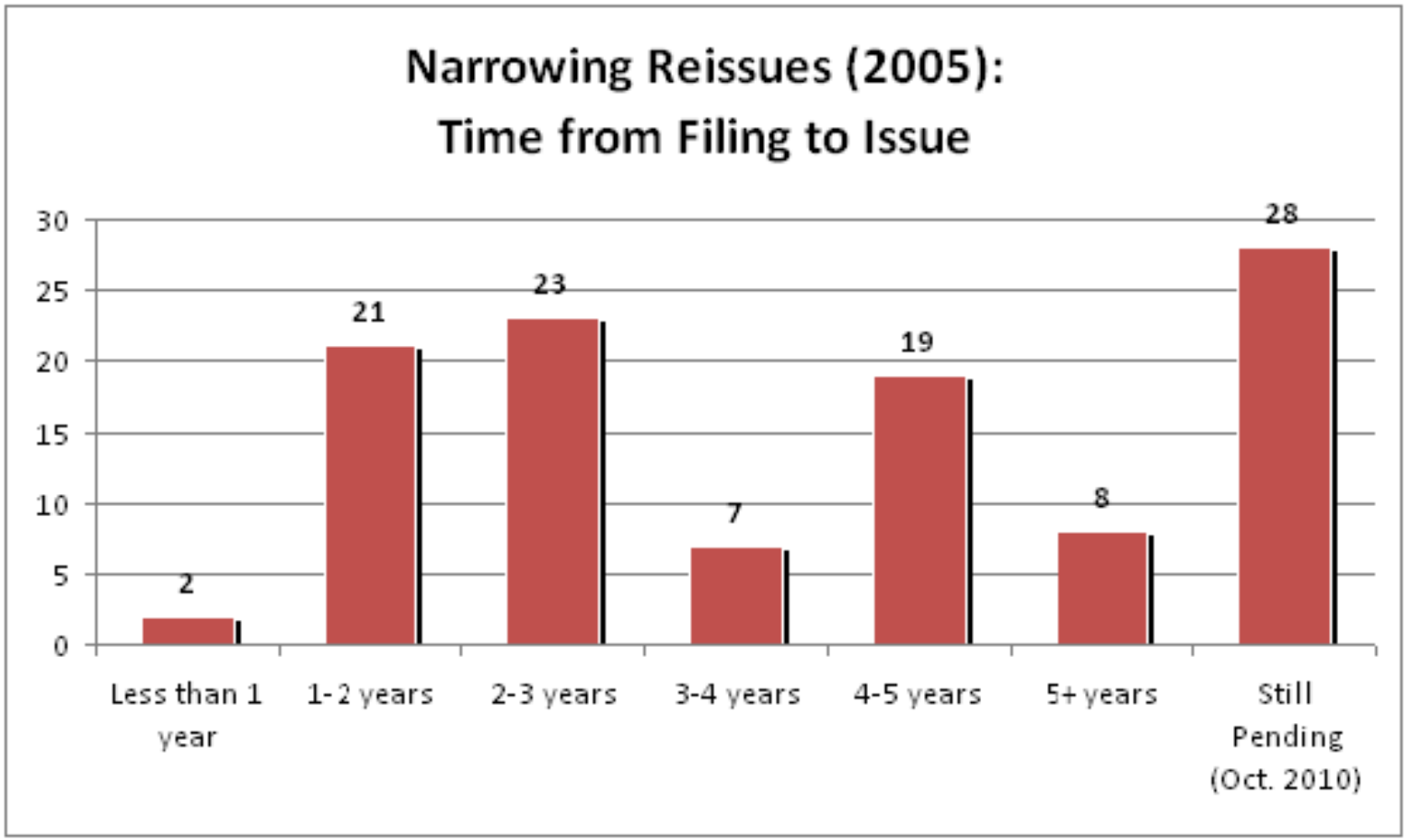
200 Abandoned (not shown)

20% complete within 3 yrs

Narrowing Reissue

- Examining Corps
- Oath Issues (add 1 year)
- Amendment style mistakes
- **Pendency?**
- **Far less common than broadening**
- Merger purpose? (Claims killed elsewhere?)
- Query: Is reexamination the better mechanism?

Narrowing Reissue



129 Total

80% concluded within 5 yrs.

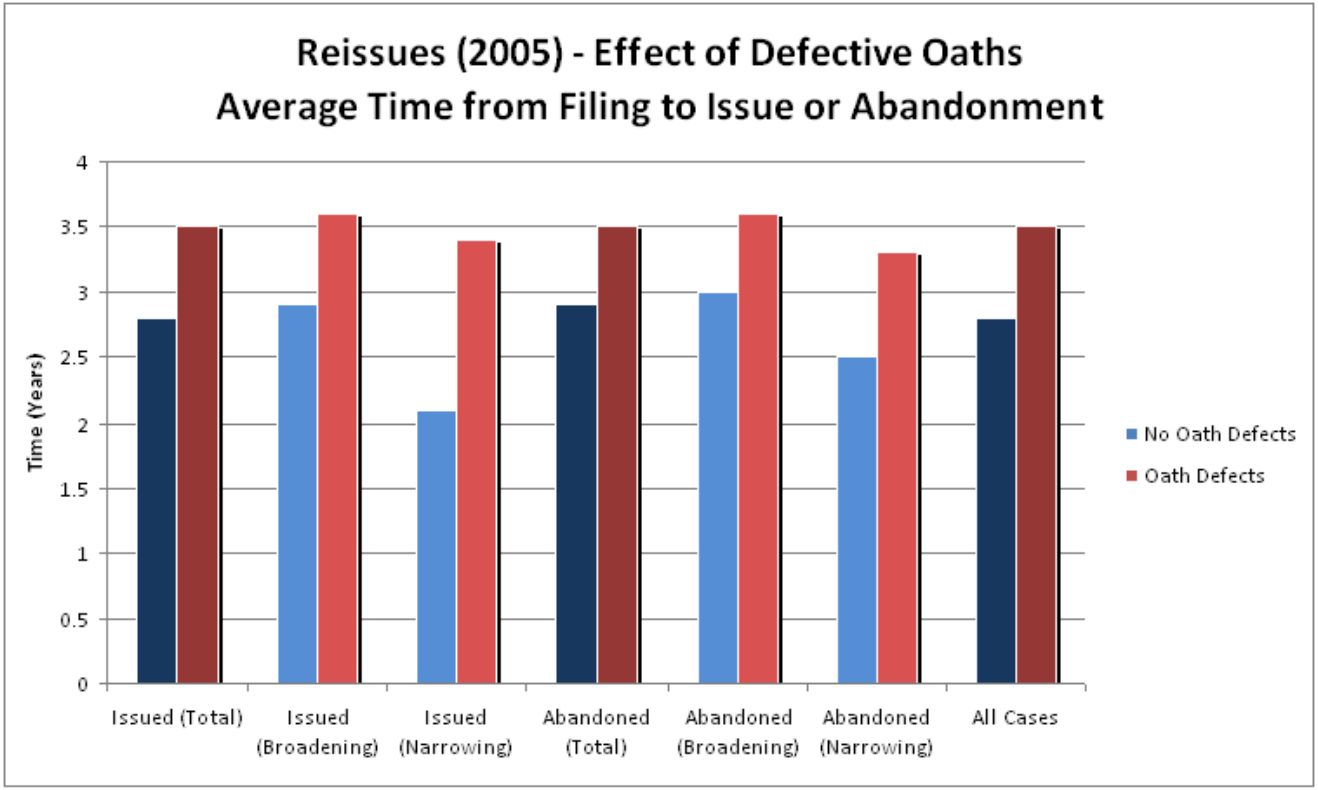
Add 1 year for oath problems

****Abandonments not counted**

Oath Mistakes

- Beware box checking
  - Claiming “more or less”
- Lack of specificity
- Inconsistent treatment across art units
  - Reissue QAS
  - Examiner in the middle, talking to the wrong person
  - Examiners not familiar, supervisors drive delay

Oath Delays



Avoiding Delay?

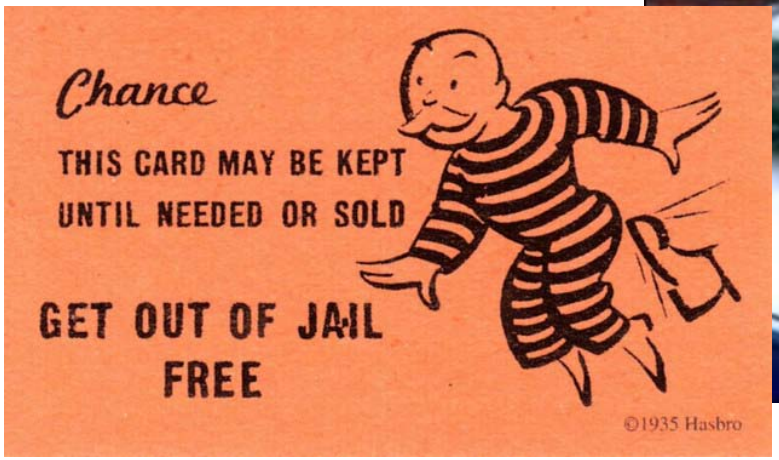
- For narrowing reissue applications filed in 2005, applications without any oath problems were completed 1.14 years faster (1.74 vs. 2.88 years) than those with oath problems.
- 70% of patent reissue filings include a defective oath.

A Better Way?
Duty of Disclosure

- Ex Parte Reexamination –Owner Initiated
  - Special dispatch (SE as well)
  - CRU (not reissue)
  - Focused review (3 SPEs), limited claims
  - Owner statement/request with claim changes
  - 12 month turnaround?
  - SNQ?
- Some risk (no EOTs or RCE)
- But, can always seek reissue if you fail.
- Reissue is only option to broaden

Choices

- Consider Reissue, EXP and SE
- Impact on infectious unenforceability?
  - Reissue continuations
  - Merger?...stalking reissue filing
- Need?
- Cost?
- Speed?
- Ethics?



Thank You

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