

DELVACCA PRESENTS

New Challenges to U.S. Patents under AIA - Strategies and Considerations

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USPTO Pre/Post-Grant Proceedings under the AIA

- Pre-Grant Submissions (modified)
- Supplemental Examination (new)
- *Ex Parte* ReExam (modified)
- Post-Grant Review (new)
- *Inter Partes* Review (replaces *Inter Partes* ReExam)
- When and why to utilize?

Pre-Grant Submission (“PreGS”)

PreGS

- Authority: New 35 USC §122(e) and proposed Rule 290
- Replaces:
 - Rule 99 filing (filed within 2 mos. of pub.; no comment)
 - Protest Under Rule 291 (filed prior to publication)

PreGS: When to file:

(1) Prior to NOA, and

(2) Prior to later of

- (a) 6 months after publication under §122, or
- (b) the date of a first rejection (on the merits).

PreGS: What to file:

- Patents, published applications, other publications
- Document does not have to be prior art
- “Concise” Description of Relevance of each document, *i.e.*, more than a general statement.
- Evidence of document publication date; translations.
- Fee if more than three documents submitted.
- Other formalities.
- No limit on the number of documents

PreGS: Effective date

- September 16, 2012
- Applies to any patent applications “filed before, on or after” September 16, 2012.

PreGS: Advantages/disadvantages

- Advantages:
 - Cheap, easy and anonymous; no estoppel to submitter
 - Force applicant to amend claims
 - Force applicant to make arguments creating estoppels
 - No limit on number of documents submitted
 - No SNQP standard
- Disadvantages
 - No participation by submitter beyond original submission
 - The Examiner could misconstrue your submission.
 - Could end up strengthening patent
 - Perhaps don't submit best prior art

Ex Parte Reexamination

Ex Parte Reexamination

Positive Features

- Lower cost than inter partes proceedings (Av. \$19,000 vs. \$128,000 – source AIPLA 2011 Economic Survey), especially if handled in-house; current filing fee is \$2,520
- Threshold for institution is low – substantial new question of patentability
- Special Dispatch (Est. time 2 years)
- No estoppel in later USPTO or court proceedings
- Favorable claim interpretation – claims given broadest reasonable interpretation
- Preponderance of evidence standard
- Intervening rights available
- Third party may remain anonymous

Negative Features

- No participation by third party requestor beyond initial request
- Patent owner may amend claims to avoid art
- No right of requestor to terminate proceeding (e.g. as part of a settlement)
- Patentee interviews available

EPRX: Unchanged Provisions

- Available to 3rd parties and the patent owner
- Requestors may submit “prior art consisting of patents or printed publications”
- Legal standard of review is still “substantial new question of patentability”

EPRX: Major Changes

- Limited loss of requestor's anonymity
- Limited consideration of patent owner's statements as to claim scope
- EPRX prohibited if patent is or has been subject to Inter Partes Review or Post-Grant Review
- Clarification that exclusive route of review is BPAI and CAFC.

EPRX: Patent Owner Statements

- Includes any position taken by PO as to claim scope in Federal court or USPTO proceeding
- Deposition transcriptions may be considered
- PO may submit explanation of “how the claims differ” from any previous statement

EPRX: Estoppel Certification

- Anonymity could circumvent AIA estoppel provisions otherwise applicable to EPRX requester who participated in a PRG or IPR.
- Requestor must certify that estoppel provisions of PGR or IPR do not bar EPRX request by:
 - Requestor;
 - the real party in interest; and
 - any privies
- Requester identity not revealed to POI.

Supplemental Examination ("SPEX")

SPEX: Overview

- SPEX is entirely new
- Only patent owner may request SPEX
- Patent owner may request SPEX “to consider, reconsider, or correct information believed to be relevant to the patent”
- Can cure unenforceability as to any information considered/reconsidered/corrected in SPEX

SPEX: Patent Owner's Request (1)

- Patent owner may submit up to ten items of information with single request for SPEX
- Patent owner may submit more than one request for SPEX

SPEX: Patent Owner's Request (2)

- Unlike EPRX, items of information are not limited to “prior art patents and printed publications”
- Items of information may be audio or video transcripts

SPEX: Patent Owner's Request (3)

- Patent owner must explain in detail why each item of information:
 - was not previously considered;
 - should be reconsidered; or
 - was incorrect during prior examination but is presently corrected
- Proposed rule 1.610(b)(8)) will require a detailed explanation for each identified issue, discussing how each item of information is relevant to each aspect of the patent identified for examination, and how each item of information raises each issue identified for examination

SPEX: Patent Owner's Request (4)

- Patent owner may submit explanation as to why each item of information does not raise a substantial new question of patentability
- Amendments to patent and interviews are not permitted before order of reexamination

SPEX: Consideration of Request

- USPTO will consider whether patent owner's request raises a substantial new question of patentability (within 3 mos. of SPEX request).
- If substantial new question of patentability raised, USPTO will order reexamination.
- Patentee cannot make submission regarding the art or claims before the 1st office action in the reexam.

SPEX: Reexamination Procedures

- Reexamination following SPEX generally follows EPRX procedures
- Cost:
 - \$5,180 for initial request, plus \$16,120 for ex parte reexam proceeding (\$16,120 refunded if no reexam is ordered).
 - No small entity discount in proposed rules

SPEX: Purge Inequitable Conduct

- A patent shall not be held unenforceable on the basis of conduct relating to information that has 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***". AIA §257(c)(1).

SPEX: 1st Exception to IE Purge

- SPEX filing to rectify IE barred if predated by allegation of inequitable conduct, pled with particularity, in:
 - civil action, or
 - Par. IV ANDA patent certification notice.

SPEX: 1st Exception to IE Purge

- Will be rarely applicable because
 - Basis for IE by an opponent is not usually unearthed until discovery phase in litigation.
 - Prior to threatening litigation or precipitating DJ action, Patentee can file SPEX request to absolve the inequitable conduct.

SPEX: 2nd Exception to IE Purge

- Directors' certification from an SPEX or reexam ordered therefrom, must be completed before an action for patent infringement under §281 or unfair competition §337(a) of the Tariff Act.
- Advantage to patentee: Patentee controls the timing of bringing suit, and will delay enforcement until completion of the SPEX/reexam.

SPEX: 3rd Exception to IE Purge

- Referral to US AG if “a material fraud on the Office may have been committed” in connection with the patent under SPEX.
- Director already has criminal referral power. It is rarely used.
- Criminal liability for false statement in original prosecution likely barred by 5-year Stat. of Lim. under 18 USC 1001.

SPEX: Conclusion

- SPEX can be used to:
 - cure simple oversights
 - cure intentional failures to disclose prior art by parties subject to the duty of disclosure
 - submit any other information that could form the basis of an IE charge in litigation
 - avoid need to present “unattractive” witness/inventor

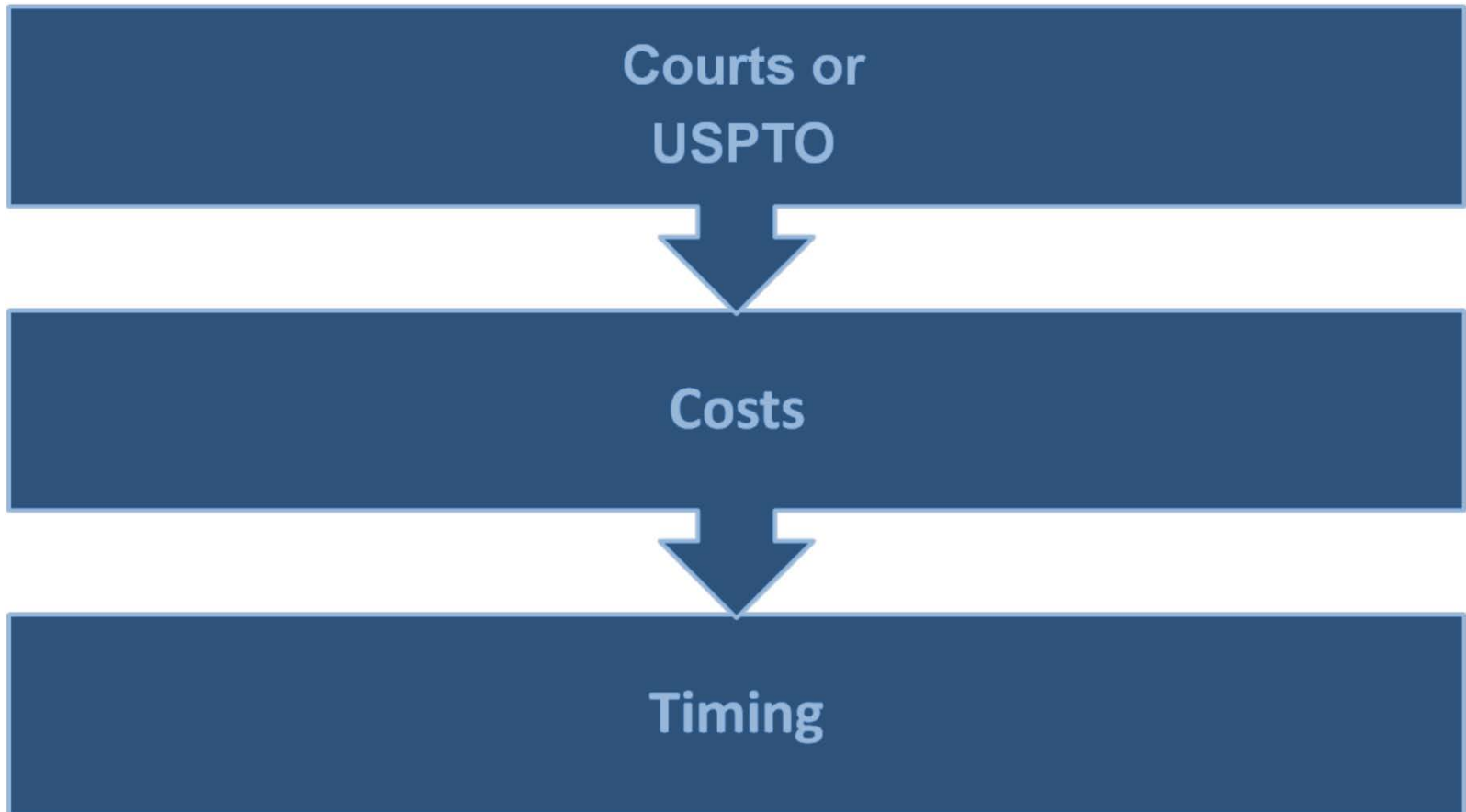
Hypothetical:

You are about to announce introduction of a new product June 1, 2012 and become aware of a patent with relevant claims. The patent issued in Dec. 2011 and was filed after Nov. 29, 1999. You have found a highly relevant printed prior art publication. What are your options to challenge validity in the USPTO?

- Ex Parte Reexamination
- Inter Partes Reexamination (Available Until 9/16/2012)
- Inter Partes Review (Available 9/16/2012)
- Post Grant Review (Available for patents filed on or after 3/16/2013)

Post-Grant Review and *Inter Partes* Review Proceedings

Options and Considerations for Challenging Patents



USPTO Procedures vs. District Court Litigation

- Framework of estoppel/stays/timeframes/cost creates complexity
- Final rulemaking has not been published
- Major considerations in each particular situation
 - Is the PTO a more attractive forum than district court?
 - Which PTO proceeding is most advantageous?

USPTO Procedures vs. District Court Litigation

Factors that may be determinative

- Timing : Within 9 months of grant?
- Complexity of technology
- Can estoppel be tolerated?
- Has a thorough prior art search been conducted?
- Is settlement reasonably possible and/or desirable?
- Is the level of discovery available in PTO procedures sufficient?
- Facts and Evidence :
 - Will evidence prove invalidity under preponderance of evidence standard or under clear and convincing evidence standard?
 - Is evidence supporting invalidity based on reasons other than lack of novelty/obviousness?
 - Is there evidence of invalidity other than a patent or printed publication?

Court Proceedings

- Infringement litigation
 - Sue or wait to be sued?
 - DJ jurisdiction available?
 - Counterclaims available?
 - Challenged patent entitled to presumption of validity
 - Party challenging patent has “clear and convincing” burden of proof

Court Proceedings

- Audience
 - Article III judge
 - What is court's experience with patent cases?
 - Time to decision?

USPTO Proceedings

Post Grant Review

More likely than not

101, 112, 102/103

Inter Partes Review

Reasonable likelihood

102/103

USPTO Proceedings

- Patent being challenged not entitled to presumption of validity
 - Claims given “broadest reasonable interpretation”
 - But, 35 U.S.C. § 301 speaks in terms of “proper meaning of a patent claim”
 - May need to wait for courts to deal with this
 - Standard of proof: lower than “clear and convincing”
 - Post-grant review standard is “more likely than not” that challenger will prevail
 - *Inter partes* review standard is “reasonable likelihood” that challenger will prevail (lowest standard)
- DJ jurisdiction not an issue
 - Potential defendant can strike first

Strategic Use of Post Grant Review

Basic Considerations:

- Applicable to Issued Patents Having an Effective Filing Date of March 16, 2013 or Later
- Request for Post Grant Review Must be Made During 9 Month Window From Grant
- Assuming at Least a 1 Year Prosecution Period, Post Grant Review Petitions Are Not Likely to be Filed Until at Least 2014

USPTO Proceedings

- Duty of candor applies
 - May require petitioner to submit non-cumulative information inconsistent with position advanced by petitioner, and point out relevance and pertinence to claims being challenged

USPTO Proceedings

- Audience
 - Administrative Patent Judge
 - More facile with claim interpretation issues?
 - More facile with technology issues?
- Time to decision

Costs

- Post-Grant Review and *Inter Partes* Review
 - \$40k - \$50k PTO fees
 - Attorney fees
 - Costs for discovery
- District Court
 - Attorney fees
 - Costs for discovery

Timing

Inter Partes Review will be available on 9/16/12 for the pre-Nov 1999 issuances that could not be brought under *Inter Partes* Reexamination

Post-Grant Review will be available on patents issued under first-to-file; won't be available until March 2014 (prioritized exam), more likely March 2016

Post-Grant Review

Post-Grant Review Proceedings

- Creates a nine-month window in which the patentability of a patent can be reviewed.
- Instituting post-grant review requires a threshold showing that it is “more likely than not” that at least one of the claims challenged is unpatentable.
- Generally limited to patents for which the first-inventor-to-file provisions apply.

Post-Grant Review

- What is the scope of the challenge?
- Petitioner may raise any ground that may be raised under paragraph (2) or (3) of 35 U.S.C. 282 (b).
- Any claim of the patent can be challenged on any basis, including:
 - lack of novelty or obviousness over the prior art
 - lack of enablement
 - lack of written description
 - claim indefiniteness
 - lack of utility
- Significant departure from existing reexamination regime, which is limited to consideration of prior art patents and printed publications

Post-Grant Review

- **Initial Threshold.** Following the initial submission, the PTO must determine that the initial showing, if not rebutted, would demonstrate it is “more likely than not” that at least one claim is unpatentable
- **Burden of Proof**
 - Patentability is determined based on the preponderance of the evidence standard
 - This is a substantially lower burden than the “clear and convincing” standard required for proving patent invalidity in district court

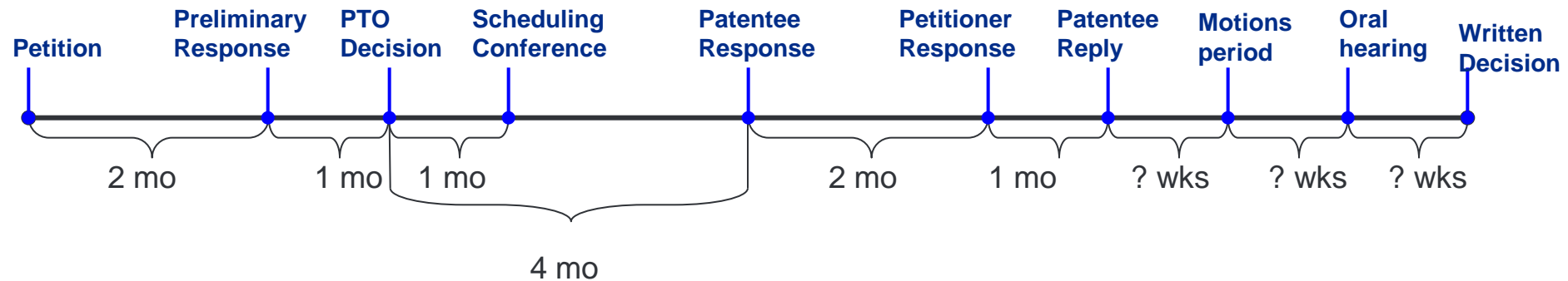
Post-Grant Review

- **Patent Owner Amendment.** The patent owner may amend the claims only once as a matter of right; afterwards, only on a showing of good cause
- **Limitations.** A third party cannot seek Post-Grant Review if it has already filed suit in district court to challenge the patent

Post-Grant Review

- **Completion of Case.** The proceeding must be completed in one year from commencement, or within 18 months based on good cause shown
- Two years at most
 - 6 months institution
 - 12 months review
 - 6 months “good cause” exception

Hearing Timeline



Post-Grant Review

- **Preclusive Effect**

- The challenger is barred from later raising issues that were raised or reasonably could have been raised in the Post-Grant review

Discovery

- Some form of discovery will be available (*e.g.*, depositions)
- It will be possible to submit expert declarations

Intervening Rights under Post Grant Review, *Inter Partes* Review and *Ex Parte* Reexamination – A real weapon

- Obtain Stay of Litigation
- Avoid injunction
- Reduce Settlement Costs
- Avoid Willfulness Finding
- Ability to Collect Past Damages is Eliminated
- Amendments Can Surrender Damages
- Surge in Ex Parte and Inter Partes Reexamination Filings since 2002.
- Good Percentage of those Request involve Patents in Litigation (IPRx (2011) 75% and ExPRx (2011) 46%)
- PTO Outcomes (2011)
 - Ex parte: all claims confirmed = 16%, all claims canceled = 10%, claims changed = 74%
 - Inter partes: all claims confirmed = 13%, all claims canceled = 37%, claims changed = 50%

Costs

- Costs---\$40k-\$50k plus attorney fees
- Attorney fees
 - Will vary with subject matter, discovery, motions

Post Grant Review

Interim Strategy

- Institute robust watch program to monitor prosecution history of patent applications of interest/claim amendments
- Begin assembling evidence for validity challenge based on novelty, obviousness, lack of enablement and inadequate written description in light of prosecution history
- Consider sources such as trade literature not normally searched by the USPTO, possibility of on sale bars

Inter-Partes Review

Inter Partes Review

- Effective on the day of enactment, the threshold for granting an *inter partes* reexamination was changed from a “substantial new question of patentability” to a higher threshold of “reasonable likelihood that the requester would prevail.”
- One year after enactment, *inter partes* reexamination will be replaced by “*inter partes* review”, which retains the “reasonable likelihood” threshold
- *Inter partes* review proceedings will be adjudicated by the Patent Trial and Appeal Board from start to finish.
- The Director may limit the number of petitions to institute IP review during the first 4 years.
 - Not likely this will happen.

Inter Partes Review

- **Who?**
- Any third party may petition for a review of the patentability of an issued patent

- **When?**
- After the later of 9 months from issuance of the patent or termination of a post-grant review of the patent

Inter Partes Review

- **Scope?**
- Limited to patents and publications, and issues of novelty and non-obviousness
- Petitioner may only raise grounds under 35 U.S.C. 102 and 103 and only on the basis of prior art consisting of patents and printed publications.

Inter Partes Review

- **Completion of Case.** The proceeding must be completed:
 - within one year from commencement, or
 - within 18 months based on good cause shown
- **Preclusive Effect.** The challenger is barred from later raising issues that were raised or reasonably could have been raised in the *Inter Partes* review

Inter Partes Review

- **Limitations.** A third party cannot seek *Inter Partes* Review:
 - If it has already filed suit in district court to challenge the patent, or
 - Later than one year after it has been sued by the patentee in district court for patent infringement

Inter Partes Review

- **Settlement**

- Parties have right to settle and terminate *inter partes* review so long as the PTO has not decided the merits of the proceeding
- Settlement is not an option under *inter partes* reexamination

**Should you beat September 16, 2012 start date
for *Inter Partes* Review?**

Inter Partes Review

- 40k-\$50k plus attorney fees
- discovery—interrogatories, document production, depositions, cross-examination, hearing as a matter of right with live witness
- 2 years max (no examiner)
- Raised or could have raised
- Reasonable likelihood

Inter Partes Reexam

- \$4.5k (\$2.5k examiner + \$2k Board) plus attorney fees
- no discovery
- slow (3 – 4 years)
- raised or could have raised
- reasonable likelihood

Comparison of Inter Partes Procedures

Similarities

- Requestor is other than the patent owner
- Real party in interest must be named
- Novelty and obviousness issues only based on printed publications and patents
- Standard for granting request: reasonable likelihood that petitioner will prevail with respect to at least one claim

Comparison of Inter Partes Procedures

Differences

Inter partes Reexamination

- 1-Patents filed after 11/29/1999
- 2-May respond to patentee's arguments
- 3-No discovery opportunity
- 4-Requestor may not terminate proceeding
- 5-Estoppel in civil actions as to claim that was raised or could have been raised by requestor

Inter partes Review

- 1-Any unexpired patent
- 2-May submit declarations of supporting evidence
- 3-Limited discovery: deposition witnesses submitting declarations and what is necessary in the interest of justice
- 4-Can be terminated by settlement between parties
- 5-Estoppel in civil actions, USPTO, ITC proceedings as to a claim that was raised or reasonably could have been raised by requestor

Comparison of Inter Partes Procedures Differences

Inter Partes Reexamination

6-Requests may be made up to
Sept. 16, 2012

7-Decided by Central
Reexamination Unit

Inter Partes Review

6-Requests may be made Sept.
16, 2012 and thereafter; and
after the later of 9 months from
grant or termination of a post
grant review proceeding; may
not be initiated if request filed
more than one year after
requestor served with
infringement complaint; may not
be initiated or maintained if
requestor has filed civil action
challenging validity

7-Decided by Patent Trial and
Appeal Board

Comparison of Inter Partes Procedures Differences

Inter partes Reexamination

- 8-May amend claims without motion
- 9-No statutory time limit
- 10-Appeal to Board of Patent Appeals and Interferences, then to Federal Circuit
- 11-Estoppel only after issuance of reexamination certificate, i.e. after no possibility of further proceedings
- 12-Litigation stays – patent owner may obtain stay of pending litigation
- 13-Filing Fee/Cost- Significantly lower than projected for Inter Partes Review

Inter partes Review

- 8-Patent owner may once file one motion to cancel or amend claims – without enlargement of scope
- 9-Final determination no later than 1 year after institution of proceeding
- 10-Appeals go to Federal Circuit
- 11-Estoppel after Board issues final written decision, i.e. before issuance of certificate
- 12-No provision for stays
- 13-Cost to file/maintain is substantially greater than for Inter Partes Reexamination, in excess of \$50,000 for filing fee/additional expense for discovery, depositions, etc.

Additional Considerations

- Has the patent owner engaged in threatening actions? Can you file a declaratory judgment action? Timing considerations related to filing of inter partes review/declaratory judgment action
- Are there design around options and what is the timeframe needed to develop them?
- Are there patents/patent applications/non-patent causes of action useful for settlement purposes?
- Will an adverse decision in inter partes proceeding support a willfulness charge?
- Pre-Post Grant Review Dead Zone – no inter partes review within first 9 months of issuance for most patents for several years; only PTO procedure available will be ex parte reexamination during 9 month period
- Prior user rights

Likely Impact of Available Challenges

- After grant, the patentee may be subject to Post-Grant Review or *Inter Partes* Review, significantly increasing the burden of maintaining a patent portfolio
- Patent challengers will be attracted to these proceedings by their low cost and speed, compared to district court patent litigation
- As a result, the focus of patent validity challenges may be shifted from federal district court patent litigation to the new PTO proceedings

Likely Impact of Available Challenges (2)

- Civil action filed by petitioner in post-grant review or *inter partes* review will automatically be stayed
 - No stay if patent owner counterclaims for infringement
- Not likely this will come up much in practice

Likely Impact of Available Challenges (3)

- Discovery in district court broader than in PTO
 - Solid §102 or §103 reference may mean little to no other discovery is needed to support PTO challenge
 - Post-grant review discovery limited to evidence related to factual assertions
- DJ action or counterclaim in district court litigation may be preferable

Likely Impact of Available Challenges (4)

- A reference that invalidates at least some claims in PTO may give rise to inequitable conduct claim if challenger can show patentee knew about it and made decision to withhold it
 - Reference that invalidates claims likely to be considered material in later district court action
- Conversely, if reference fails to invalidate claims in PTO, patentee may be able to argue that any alleged infringement by party challenging patent was willful

Intervening Rights

- Are there intervening rights?
 - Court action may give effect to such rights
 - Patentee should consider possible effect on intervening rights when deciding whether to amend claims

Intervening Rights under Post Grant Review, *Inter Partes* Review and *Ex Parte* Reexamination – A real weapon

- Intervening Rights – Each of PGR, IPR and ExPRx
- Avoids “gross injustice”
- Provides License to Continue to Use Products Previously Made If Infringing Under Changed Claims (35 USC §§ 307 (ExPRx) (1980), 316 (IPRx) (1999))
- Patent Claims Require “substantive changes”
- Absolute: No liability if Product made before Reexam
- New 35 USC §§ 318(c) and 328(c) create intervening rights for PGR and IPR under same “amended or new” standard.
- Chance for Gamesmanship

Get ready

- Set up systems for monitoring and challenging competitor published applications and issued patents

- Prepare to defend against challenges against your own patents and published applications

Thank you!

Questions?

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