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Inter partes Re-examination: a Low Cost Alternative to Litigation in the US and

Prosecution Strategies in View of the Historically Low Allowance Rate at the USPTO

by

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Los Lunes de Patentes, Madrid, 30 November 2009



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- Re-exam as a low cost alternative to Litigation in the U.S.
- Obviousness and *KSR* as major factors in rejection of applications
- Strategies for dealing with KSR in various types of applications
- General prosecution tips
 - If there is time – tips for avoiding inequitable conduct...

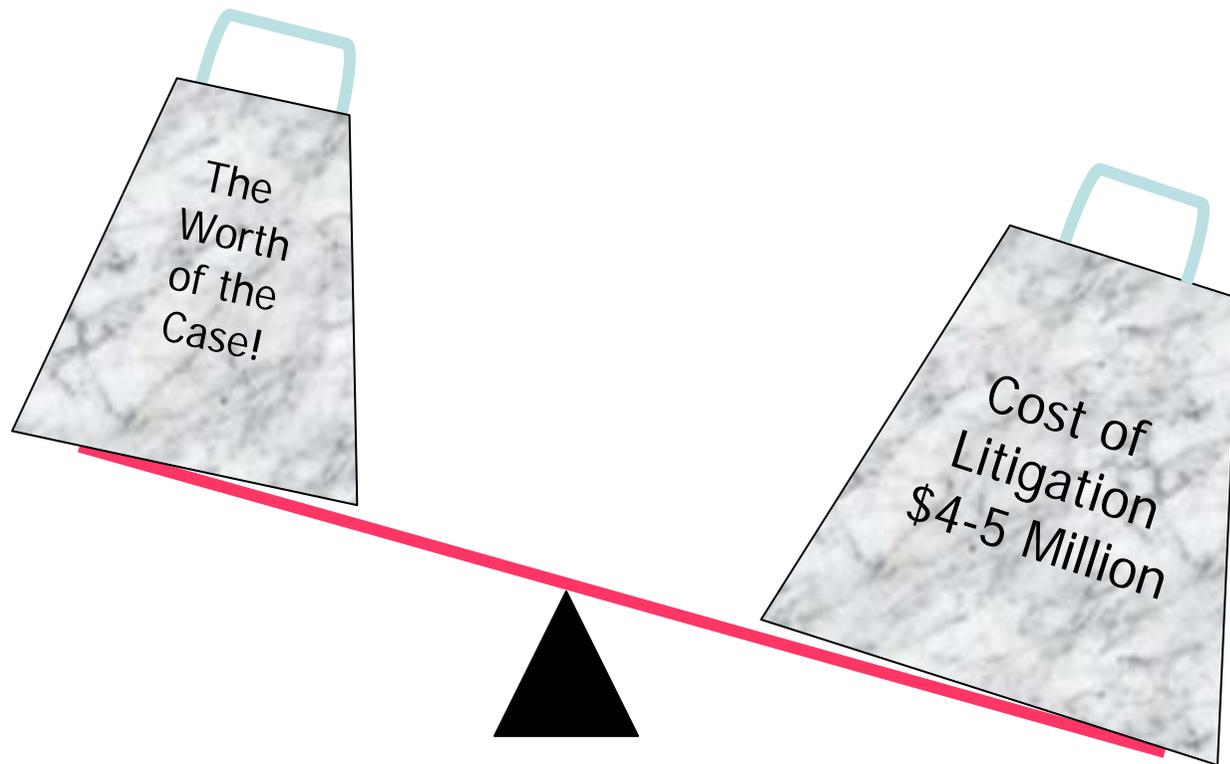
Monitoring and Detective Work

- Time and money is spent monitoring your competitors.
- Time and money is spent on searches.
- Time and money is spent investigating the scope and strength of competitor patents.
- Make this investment worthwhile.
- Balance strategies and budget.



U.S. Litigation can be expensive

- The cost of litigation is not justified in all situations.



Strategic Options

- In Europe:
 - Opposition
 - Nullity Action
 - License negotiation
- In the U.S.
 - Get an opinion and wait to get sued
 - DJ action
 - License negotiation
 - Tools available at the USPTO



Tools available at the USPTO

- 3rd Party Submissions
- Interference
- Reissue (Defensive)
- Ex parte Reexam
- Inter partes Reexam



Third Party Submissions & Protests

- **TWO WAYS TO SUBMIT PRIOR ART FOR EXAMINER CONSIDERATION**
 - (1) Third Party Submission in a Published Application (37 CFR § 1.99)
 - Within 2 months of publication or before notice of allowance
 - Limited to 10 patents/publications (no declarations)
 - No explanations of relevance
 - Applicant has no duty to respond, unless requested
 - (2) Protest by the Public Against Pending Applications (37 CFR § 1.291)
 - Before publication in U.S. or before notice of allowance
 - Can submit prior art documents and acts, e.g. prior sale, ineqt. cond.
 - Can submit explanation of relevance of prior art
 - Applicant has no duty to respond, unless requested
- **LIKELY MORE ADVANTAGE TO BE GAINED IN REEXAM.**

Interference Proceedings

- A powerful tool - unique to the U.S., but not to be feared
- Main purpose is to resolve priority of invention (35 USC § 102(g))
 - Determines which of at least two parties is not entitled to interfering patent claims
- Proceedings allow for addressing any issue of patentability, and can even address enforceability
- The proceeding may never reach priority question if no claims found patentable or enforceable during preliminary motions phase
 - Phase I: patentability and enforceability motions
 - prior art, §112, §135(b), inequitable conduct
 - not limited to printed publications
 - Phase II: priority determination
 - conception, RTP, derivation, concealment, abandonment
 - corroboration

Limitations of Interference Proceedings

- Need priority date challenge to initiate an interference
- Board will terminate (or fail to declare) any interference deemed solely a patentability attack
- Once declared, all claims in the applications/patents involved in the interference are at risk of being lost to opponent
- If true inventor, must prove inventive acts with corroboration
- Must present interfering claims within one year of date of first publication of opponent's overlapping claims
 - Need to satisfy one year statutory bar of 35 USC 135(b) to preserve future opportunity to challenge an opponent regarding the overlapping claimed subject matter
- Cost can be high, but much less than district court litigation alternative

Reissue of Original Patent (by patentee)

- Strategic Considerations
 - Opportunity to strengthen own patent (second stamp of approval)
 - Before possible litigation or licensing
 - Ex parte environment
 - Must identify an error, but need only identify one
 - Can correct errors and amend claims (broaden and narrow)
 - Cannot be used to recapture subject matter surrendered to obtain original grant
 - Broadening reissue must be filed within two years of original grant
 - Intent to broaden must be established in reissue application
 - Patent is reissued for unexpired term of original patent
 - Intervening Rights Need to be Considered

Reissue of Original Patent (by patentee)

- Advantages
 - Second stamp of approval
 - Minimal cost
 - Allows claims to be broadened (reissue application filed within 2 years)
 - Once in reissue claims can be added within scope of allowed subject matter
 - Can submit more than just patent documents for PTO consideration
 - Prior public use or sale, declarations
 - Continuation and divisional applications available
 - Can be used to seek Declaration of Interference
 - Can terminate proceeding if want out.

Reissue of Original Patent (by patentee)

- Limitations
 - Must identify an error in original patent
 - Must be “error” within 35 USC § 251
 - “Partly invalid or inoperative” or “claiming more or less than entitled to”
 - Cannot be solely to review new prior art (reexam)
 - Can be claims are too narrow or broad
 - Must change the original claims in some manner
 - Cannot cure inequitable conduct
 - Intervening rights possibly created
 - Cannot be used to extend original patent term (by deleting priority)
 - Opponent can file protest (prior art and comments)

Reexamination

- History
 - 1980 - Reexam established (*ex parte*) to serve as expedited, low cost alternative to litigation
 - 1981-1999 - Only 2150 reexams filed
 - 2000 - Still not popular; patentee generally prevails; patents made stronger through reexam
 - A strategy for the patentee!
 - As of 2001
 - 88% of patents survived *ex parte* reexam in some form
 - Only 54% survived a validity challenge in court
 - Did not make sense to file as a 3rd party!

Reexamination

- 1999 - *inter partes reexam* introduced
 - more 3rd party participation

Any better for 3rd parties?

One Congressman has observed that “the inter partes reexamination procedure places so many constraints on third-party requesters that, as some patent attorneys have stated, ‘It would be legal malpractice to recommend a client institute an inter partes reexamination.’”

149 Cong. Rec. H 5360 (Sept. 5, 2001) (remarks of Rep. Berman)

Implementation of *inter partes* Reexam

- Later significant changes were introduced
 - Introduced opportunity for third party to appeal a decision favorable to the patent owner to the Court of Appeals for the Federal Circuit
 - Provision added for both *inter partes* and *ex parte* reexamination (§ 312(a) and 303(a))
 - “The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.”

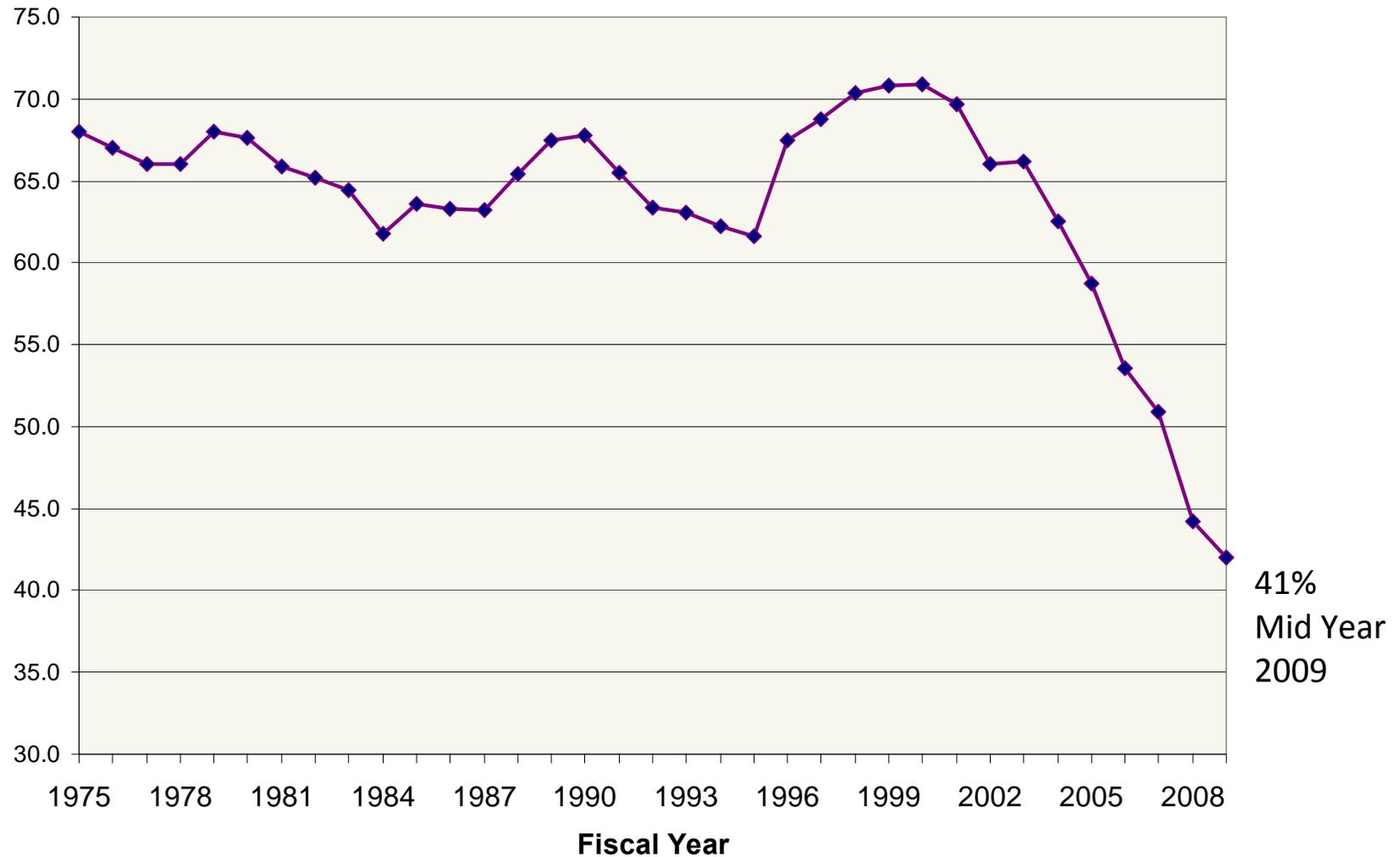
Benefits of Reexamination

- As Patentee – Get PTO Blessing of patentability over new prior art
 - Fast
 - No statement of error
 - Preparation for Litigation
 - Effects on District Court Litigation
- As 3rd Party - ?? - limited use ??
- Commissioner - Viagra

Is Strategic 3rd Party Reexam an Oxymoron?



USPTO Allowance Rate



Source: www.uspto.gov/.../ppac_2009jun18_patent_operation_update.ppt

Offensive Strategies

Use the low allowance rate to your advantage.



Inter partes re-exam!

Additional Reasons for Reexamination Becoming More Popular

- KSR impact (May 2007)
 - Many patents undergoing reexam were granted prior to KSR
 - Increases flexibility in crafting obviousness positions
 - But see M.P.E.P. § 2642(I) stating that the clarification of obviousness announced in KSR “does not alter the legal standard for determining whether a substantial new question of patentability exists.”
- Offensive attack against patent trolls
 - Contingency fee arrangements with plaintiffs’ litigation counsel sometimes exclude representation in a parallel reexamination
- Stay of parallel litigation
 - Ability to use the grant of a reexamination as a basis for seeking a litigation stay (approximately 50% of patents in reexaminations are involved in a lawsuit)
 - gain time/leverage to build/settle case
 - challenge patent validity at USPTO outside of litigation (as Congress intended)

Basis of Reexamination

- Substantial new Question of Patentability limited to patents & printed publications applied under 35 U.S.C. §§ 102 and 103.
 - (low threshold)
 - A substantial new question of patentability as to one claim is sufficient to warrant a reexamination of all claims
 - Can be based on materials previously cited to PTO
- May be filed by any person at any time during the period of enforceability of the patent.
 - Term of patent plus six years (statute of limitations for bringing infringement action (35 U.S.C. § 286)).

New Question of Patentability

- § 303(a) and § 312(a): The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.
- The claims subject to reexamination will be given their broadest reasonable interpretation consistent with the specification, and limitations appearing in the specification are not to be read into the claims.
 - *In re Etter*, 756 F.2d 852, 225 USPQ1 (Fed. Cir. 1985)
- Sole exception is reexamination involving an expired patent – claims construed to sustain their patentability.
 - *Ex parte Pabst-Motorem*, 1 USPQ2d 1655 (Bd. Pat. App. & Int. 1986)

Reexamination Strategy

- Continuing applications and RCE practice not available.
- New request for reexamination and merger with existing proceeding – see attached USPTO notice and MPEP 2283.
- File reissue application that is likely to be merged with existing reexamination proceeding – see MPEP 2285.

Reexam Basics (*ex parte* & *inter partes*)

- Conducted with “special dispatch” (2 mos. for responses)
- No withdrawal and cannot be settled once started
 - Need to consider effects on possible settlements
- Patent is in force during reexam
- Claims can be added, confirmed, amended, or canceled (but not broadened)

Reexam Basics (*ex parte* & *inter partes*)

- ***Ex Parte Only***: Can invalidate a patent previously held valid by a court, even over the same prior art
- ***Inter Partes Only***: Fast: First OA usually comes with reexam order (2 months)
- ***Inter Partes Only***: Requester always gets the last word and can appeal
- ***Inter Partes Only***: Estoppel for issues raised, or that could have been raised, in reexamination
- ***Inter Partes Only***: Third party must identify self

Reexam (*ex Parte* & *inter Partes*)

- **Possible Advantages for a 3rd party:**
 - First ruling in 3 months (very likely granted >90%)
 - Puts patent under cloud
 - Might kill or weaken patent
 - Might produce useful estoppels or admissions
 - PTO more technically sophisticated (than juries) to analyze complex patents
 - Grant of reexam may be used to establish materiality for IC
 - Standard of review low
 - Preponderance of evidence not clear & convincing

Reexam (*ex Parte* & *inter Partes*)

Disadvantages for 3rd party:

- If patent survives, it will likely be stronger
- Patent owner has opportunity to clear newly discovered prior art
- No adversarial measures (discovery, depositions) available

Inter Partes Reexamination
v.
Ex Parte Reexamination

Inter Partes Reexamination

Significant advantages for 3rd party:

1. Opportunity to comment on Office Actions and patent owner replies
2. Opportunity to appeal to both Board and Federal Circuit a decision on patentability favorable to patent owner
3. No interviews with examiner
4. Less expensive and quicker than litigation in Federal court

Inter Partes Reexamination

Significant constraints for third party:

1. Patents issuing on applications filed after November 28, 1999 only are eligible
2. Limited to issues based on patents and publications
3. Estoppels created by participation

Note: Both (1) and (3) would be amended by draft legislation that includes post-grant opposition

Reexamination Strategy Considerations

- Considerations Related to *Inter Partes* Proceedings

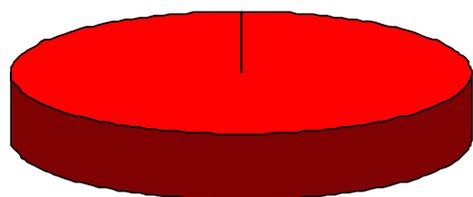
- “A third-party requester whose request for an *inter partes* reexamination results in an order under section 313 is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the *inter partes* reexamination. This subsection does not prevent the assertion of invalidity based on newly discovered prior art unavailable to the third-party requester and the Patent and Trademark Office at the time of the *inter partes* reexamination proceedings.” 35 U.S.C. § 315(c).
 - “at a later time” – this language does not appear to preclude identical assertions of invalidity in co-pending litigation
 - “could have been raised” – this language could be construed to include prior art that could have been found earlier, obviousness permutations, all possible motivations to combine, etc. not raised in reexamination
 - “unavailable...at the time” – is art that is available in a database but not found by the requester “available” at the time of the reexamination?

Ex Parte v. Inter Partes (Comparison)

	<i>Ex Parte</i>	<i>Inter Partes</i>
Requester Anonymity	<ul style="list-style-type: none"> • <i>Yes</i> 	<ul style="list-style-type: none"> • No; identify real party in interest
Time For First Action	<ul style="list-style-type: none"> • 6-11 months (average) 	<ul style="list-style-type: none"> • <i>3 – 9 months</i> (average)
Estimated Time	<ul style="list-style-type: none"> • - 2 years (appeal adds ~1.5 yrs.) 	<ul style="list-style-type: none"> • - <i>3.5 years</i> (appeal adds ~2 years)
Interview with Examiner	<ul style="list-style-type: none"> • Yes 	<ul style="list-style-type: none"> • No
Requester Participation	<ul style="list-style-type: none"> • Almost never 	<ul style="list-style-type: none"> • <i>Yes</i>
Additional Reexaminations	<ul style="list-style-type: none"> • Yes; As long as there is a substantial <u>new</u> question of patentability 	<ul style="list-style-type: none"> • OK to file another ex parte, but only one Inter Partes for Real Party in Interest (unless art could not have been previously raised)
Appeal	<ul style="list-style-type: none"> • Only Patent Owner can appeal 	<ul style="list-style-type: none"> • <i>Requester can appeal</i>
Statutory Estoppel	<ul style="list-style-type: none"> • None (but fact finder might give deference to reexam decision) 	<ul style="list-style-type: none"> • Third Party cannot later assert invalidity based on publications in later civil action

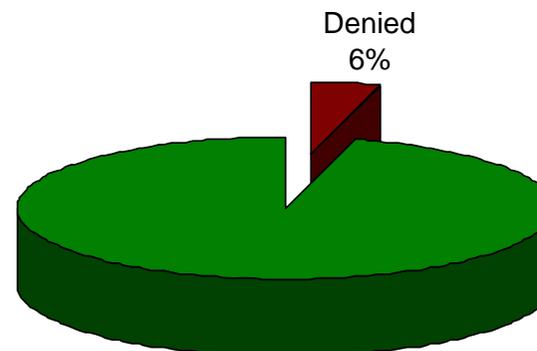
Statistics (*Inter Partes*)

Total Re-exam Requests Filed (*Inter Partes*) = 436



By 3rd Party
100%

Number of Requests Granted

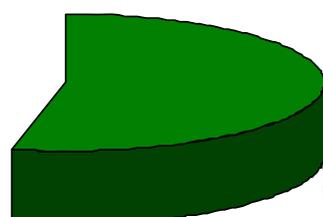
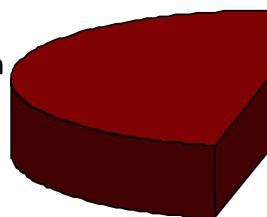


Granted
94%

Denied
6%

Number of Requests Known To Be In Litigation

Not in
Litigation
38%

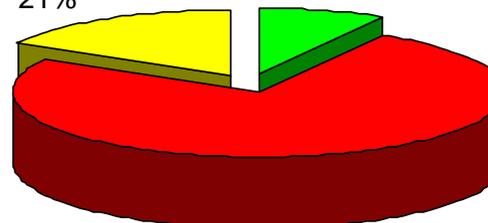


In Litigation
62%

Re-examination Certificates Issued

Claims
Changed
21%

All Claims
Confirmed
9%

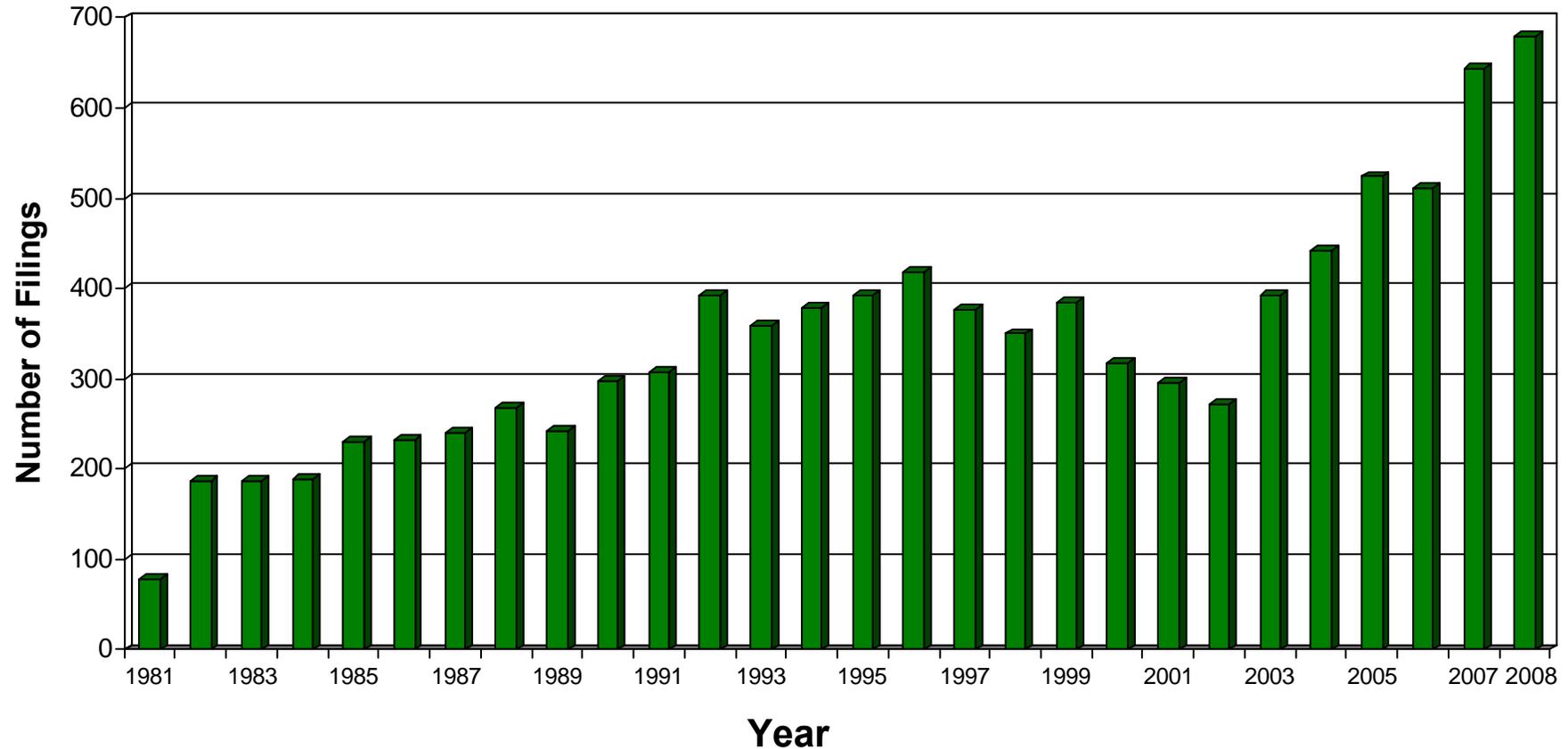


All Claims
Canceled
70%

Inter partes reexam may be more effective than you
thought...

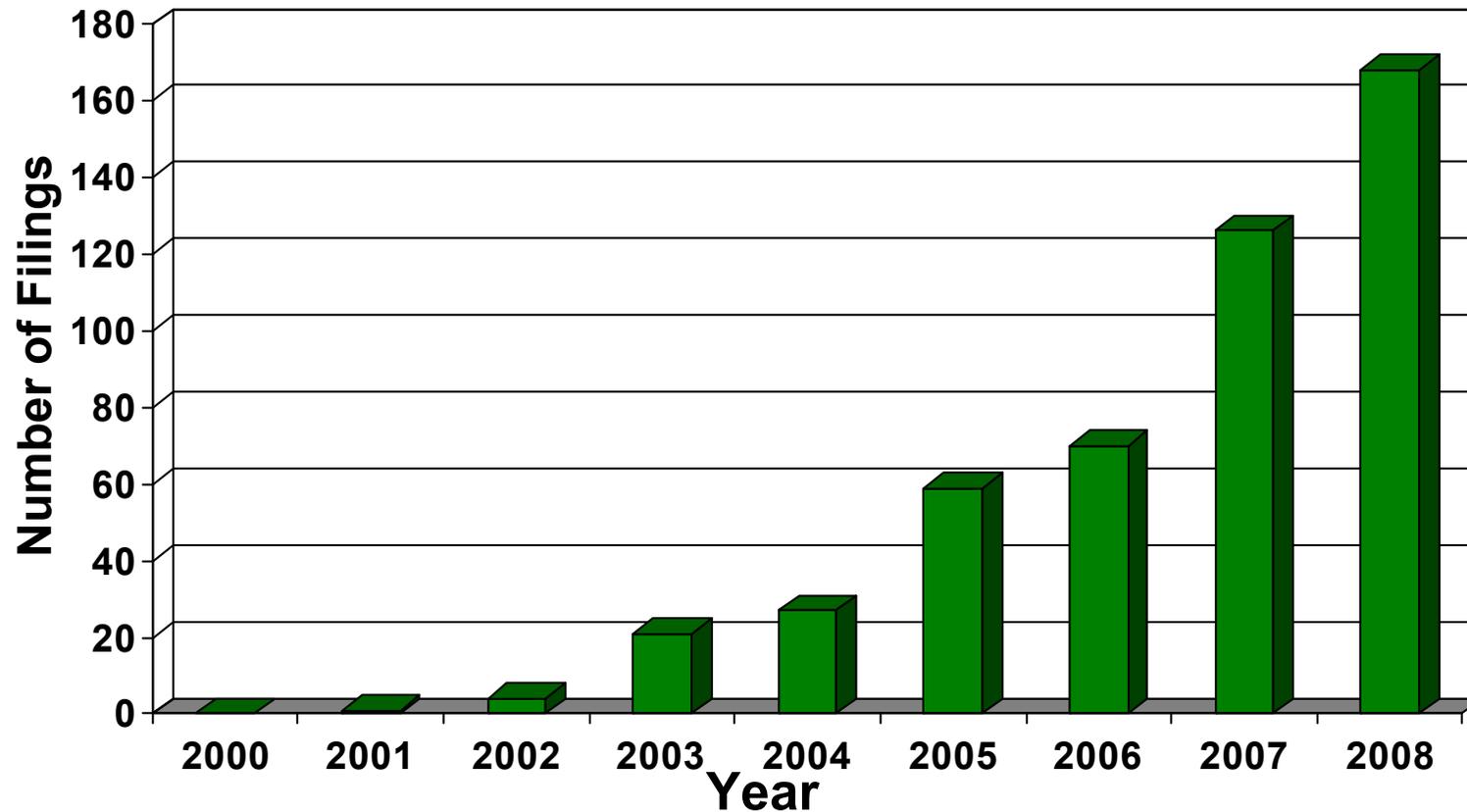
- Of the pending with at least one Office action
 - No claims rejected in only in **5** proceedings

Annual filings of *Ex Parte* Reexaminations



Data as of December 31, 2008

Annual filings of *Inter Partes* Reexaminations



Data as of December 31, 2008

Overview of Patent Reexamination Process

Patent Reexamination

PTO reconsiders patentability of issued claims

How to initiate:

Reexam Request

- Requester submits patents and/or printed publications to PTO
- The request must set forth an analysis explaining how the prior art applies to the patent claims
- If the PTO determines that the request raises a substantial new question of patentability (SNQ) for at least one patent claim, the request will be granted

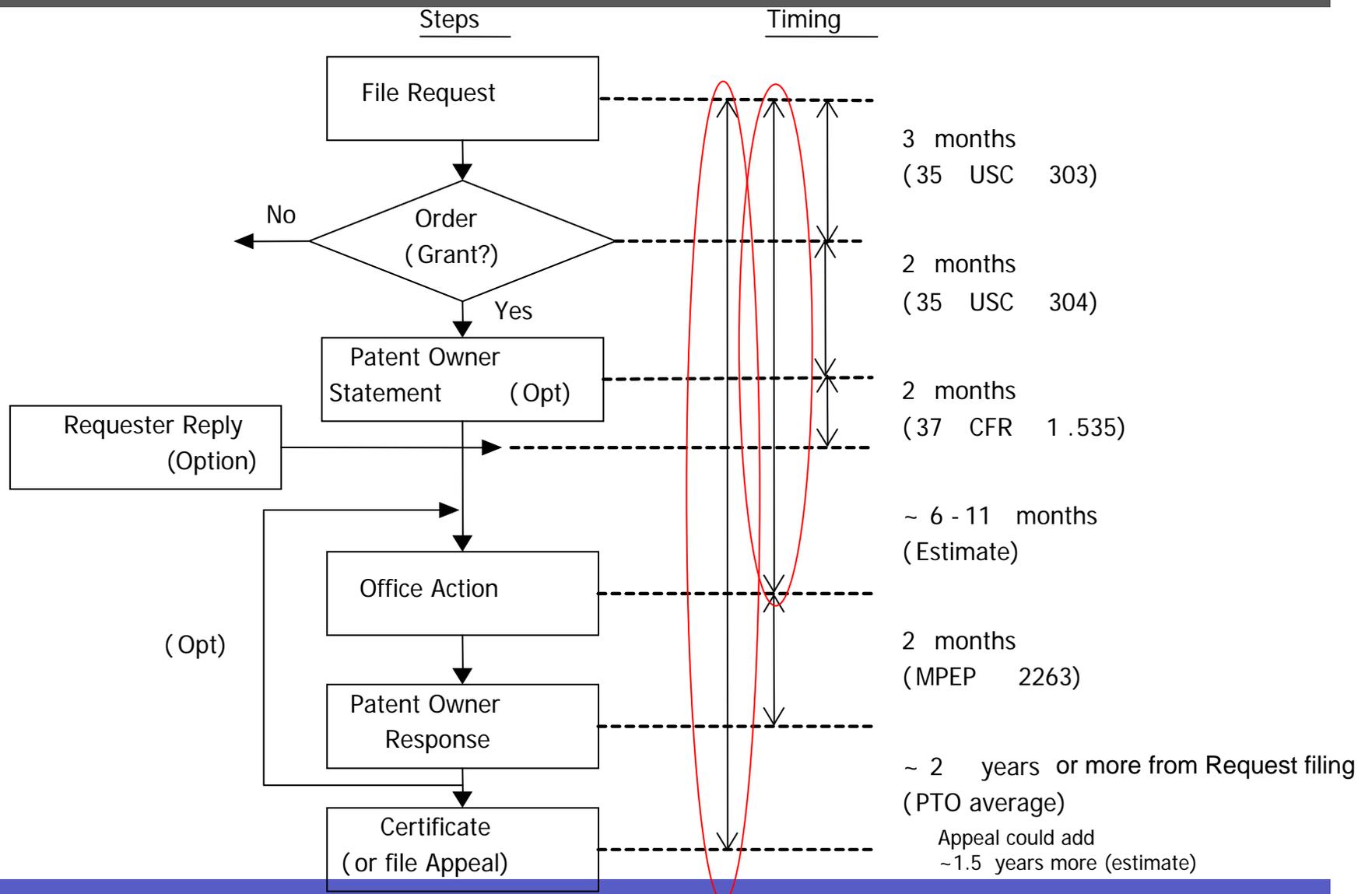
When can RFIPR be filed?

- Anytime ...
 - During enforceable life of the patent
 - Provided the patent is eligible for *inter partes* reexamination

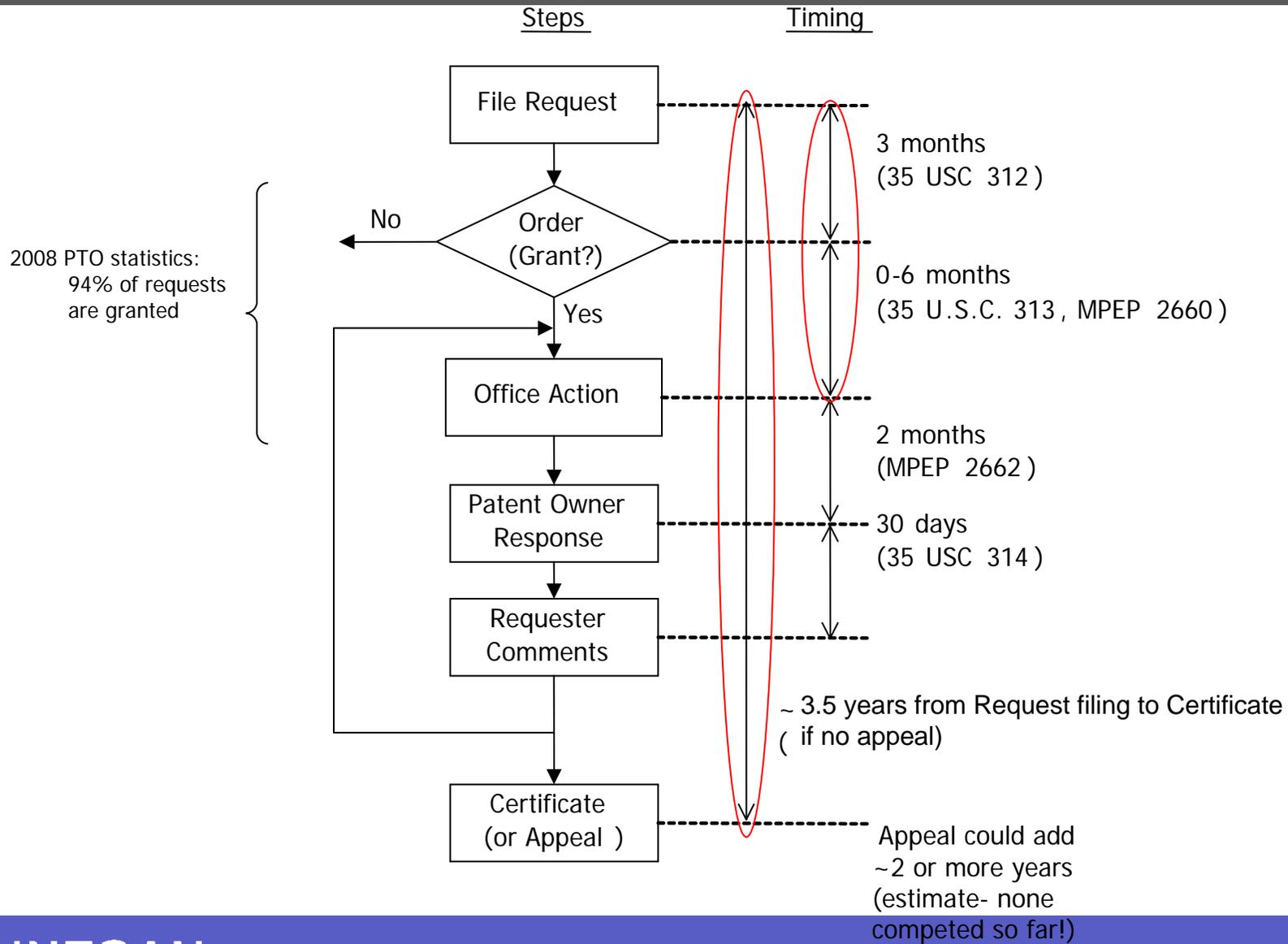
When can RFIPR be filed?

- To be eligible for *inter partes* reexamination, the patent must have issued from an “original application” filed on or after Nov. 29, 1999.
 - “Original application” “encompass[es] utility, plant and design applications, including first filed applications, continuations, divisionals, continuations-in-part, continued prosecution applications and the national stage phase of an international application.” *Cooper Tech. v. Dudas*, 536 F.3d 1330, 1331-32 (Fed. Cir. 2008)

Ex Parte Reexamination (Timeline)



Inter Partes Reexamination (Timeline)

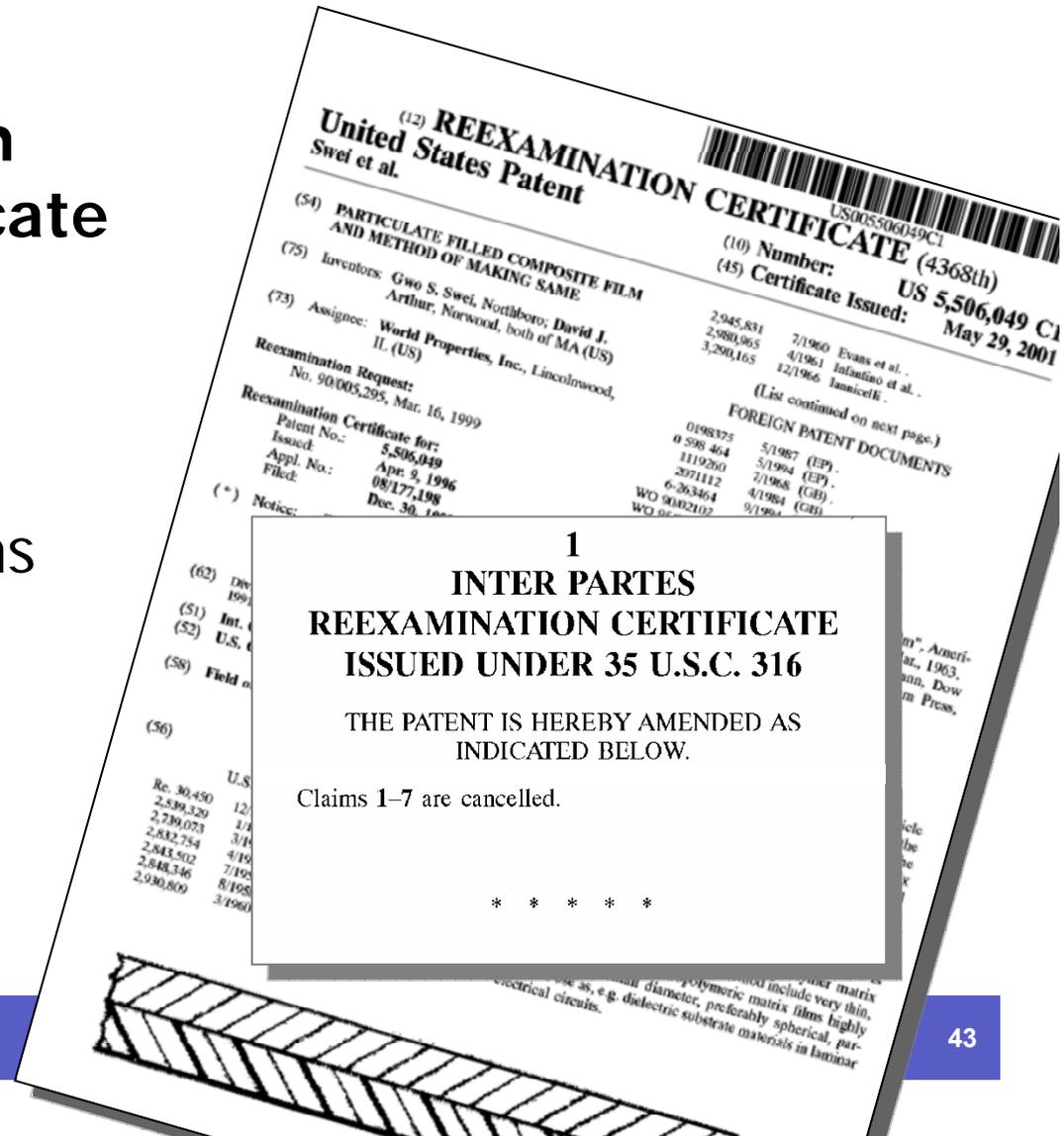


Overview of Patent Reexamination Process

Patent Reexamination

Concludes with reexam certificate identifying:

- canceled claims
- confirmed claims
- amendments



Challenging Orders Granting IPR

- Decision granting reexam cannot be challenged
 - Only recourse is to argue in the proceeding; however
...
- An *ultra vires* reexamination can be vacated
 - Petition under 37 C.F.R. § 1.181
 - Grounds
 - Not printed publication prior art
 - Estoppel
 - Final court judgment of invalidity
 - Wrong patent
 - Duplicate request
 - Same question of patentability previously considered

Situations to Consider Inter Partes Reexamination

- Claims clearly unpatentable over patents/publications
- Noninfringement case weak
- Large disparity in financial resources of companies
- Discovery would be overly burdensome
- Project does not justify cost of litigation
- Design-around a good possibility, but could be aided by additional prosecution history, intervening rights

Reasons Why Reexamination Is Often Considered As an Alternative or Supplement To Litigation

Litigation

- Multi-Millions of \$\$\$
- Presumption of validity
 - Clear & convincing evid.
- Narrow construction?
- Jury(!)

- Need to identify Party

- + Numerous grounds
 - public use/sale, 112
- +/- Discovery, depositions

Reexamination

- + Usually Much Less than \$1M
- + No presumption of validity
 - Preponderance of evid.
- + Broadest reasonable interp.
- + Experienced Examiners
 - Reexamination Group
- + *Ex parte* requester
 - can remain anonymous
- *Patent or printed pub.*
ONLY
- +/- *NO* discovery, *NO* depos.

Patent Reform Act of 2009

- Introduced in March 2009 as S. 515; H.R. 1260
- Co-sponsored by Senators Leahy (Dem.) and Hatch (Rep.) and Reps. Conyers (Dem.) and Smith (Rep.)
- Major provisions in S. 515:
 - First-to-File (sec. 2)
 - Simplified inventor's oath or declaration (sec. 3)
 - **Post-grant Review Procedures (sec. 5)**
 - Ex parte reexamination
 - Inter partes reexamination
 - **Cancellation proceedings**
 - Patent Trial and Appeal Board (sec. 6)
 - Expanded USPTO Rulemaking Authority (sec. 9)
 - Best mode requirement (Sec. 14)

U.S. Post-Grant Review Procedure

Post-Grant Review Legislation

- S. 515 Approved by Senate Judiciary Committee on April 2, 2009
- Purpose is to improve patent quality, reduce litigation expenses, and be consistent with international law
- Commerce Secretary and USPTO Director Kappos support legislation
- Full Senate debate to occur “before the end of the year” (Sen. Leahy, Oct. 5, 2009)
- Would take effect 1-year after enactment
- Possible phase-in provision limiting number of cancellation proceedings accepted by the USPTO in the first 1-4 years

U.S. Cancellation Proceedings

Requirements

- “Petition for Cancellation” for any condition of patentability -e.g. 101, 102, 103, 112, and Double Patenting, except best mode
- Petition must be filed within 12 months of issuance of patent, unless patent owner consents
- Not anonymous—petitioner must be identified
- Only one opportunity—same petitioner cannot file a second petition for cancellation of the same patent
- Analysis is on a claim by claim basis
- Applies to patents issued on or after the effective date of legislation, including reissued patents

U.S. Cancellation Proceedings

Process

- After filing of petition, USPTO decides whether to institute review within 60 days.
- USPTO decision is NOT reviewable (cannot be appealed)
- USPTO institutes review only if petition and evidence presented with petition identify a substantial question of patentability for at least one claim
- No presumption of validity; burden of proof is by preponderance of the evidence on the petitioner challenging the patent

U.S. Cancellation Proceedings

Process (cont.)

- Patent owner may file a response to the cancellation petition, including affidavits, factual evidence, and expert opinions
- Patent owner may file ONE motion to amend the patent, additional motions to amend permitted only if patent owner can show good cause
- Claim amendment cannot enlarge scope of claims or introduce new matter
- Documents filed are to become public unless they qualify to be filed under seal

U.S. Cancellation Proceedings

Process (cont.)

- Discovery limited to evidence directly related to factual assertions advanced by either party in the proceeding.
- Hearing before Patent Trial and Appeal Board, which will issue final decision
- Final decision not later than one year after date proceeding is instituted (Director can extend 6 months for good cause)
- Appeal only to Federal Circuit

U.S. Cancellation Proceedings

Process (cont.)

- Settlement will terminate proceeding and NO ESTOPPEL will apply to petitioner
- Director may stay a post-grant review if a pending civil action addresses the same, or substantially the same, questions of patentability
- Commencement of post-grant review shall not limit the right of patent owner to commence an action for infringement
- Commencement of post-grant review cannot be cited as evidence in civil action
- Petitioner estopped from raising any issue raised during the post-grant review in a future proceeding (reexam, litigation, etc) (can use any new arguments not raised in the cancellation proceeding)

Comparison of U.S. and EPO Opposition procedures

Similarities

- Can be pursued by any third party
- Either party can use experts
- Oral hearing available to both parties
- Final decision can result in total cancellation of patent, in patent with original claims, or in patent with amended claims
- Analysis is on a claim by claim basis
- Final decision is appealable by either party

Comparison (cont.)

Differences

USPTO

- Deadline to file petition is **12 months** after patent issues
- Limited discovery
- Only one opportunity to amend claims
- Settlement terminates proceedings
- Estoppel effect

EPO

- Deadline to file opposition is **9 months** after patent issues
- No discovery
- Various opportunities to amend claims
- EPO can pursue opposition on its own
- No estoppel effect (can pursue revocations in national courts)

Comparison (cont.)

Differences

USPTO

- No provisions for additional prior art search
- Duration of proceedings in USPTO is 1 year, or extended at most 6 more months
- Not anonymous
- Ground of invalidity can be indefiniteness

EPO

- EPO at its discretion can decide to carry out search
- Duration of proceedings vary, but generally longer than 1 year
- Can file opposition using a straw man
- Raising issues of “clarity” is not allowed in opposition

Implications of undergoing cancellation proceedings

- Estoppel issues
 - Not same estoppel as in *inter partes* reexamination. That is, there is no estoppel for issues that “could have [been] raised” but were not raised
 - However, still barred from raising same arguments in future proceedings, including in arguments of invalidity during litigation
 - Possible that petitioners might reserve raising some issues for litigation, along with any best mode attacks
- Discovery
 - Limited to evidence directly related to factual assertions
 - If rules mirror those of interferences, then expert testimony will be only in the form of a declaration, and discovery consists of cross examination (deposition) of the expert, but no live testimony at hearing
 - In contrast, discovery during litigation is much more extensive

Implications of undergoing cancellation proceedings

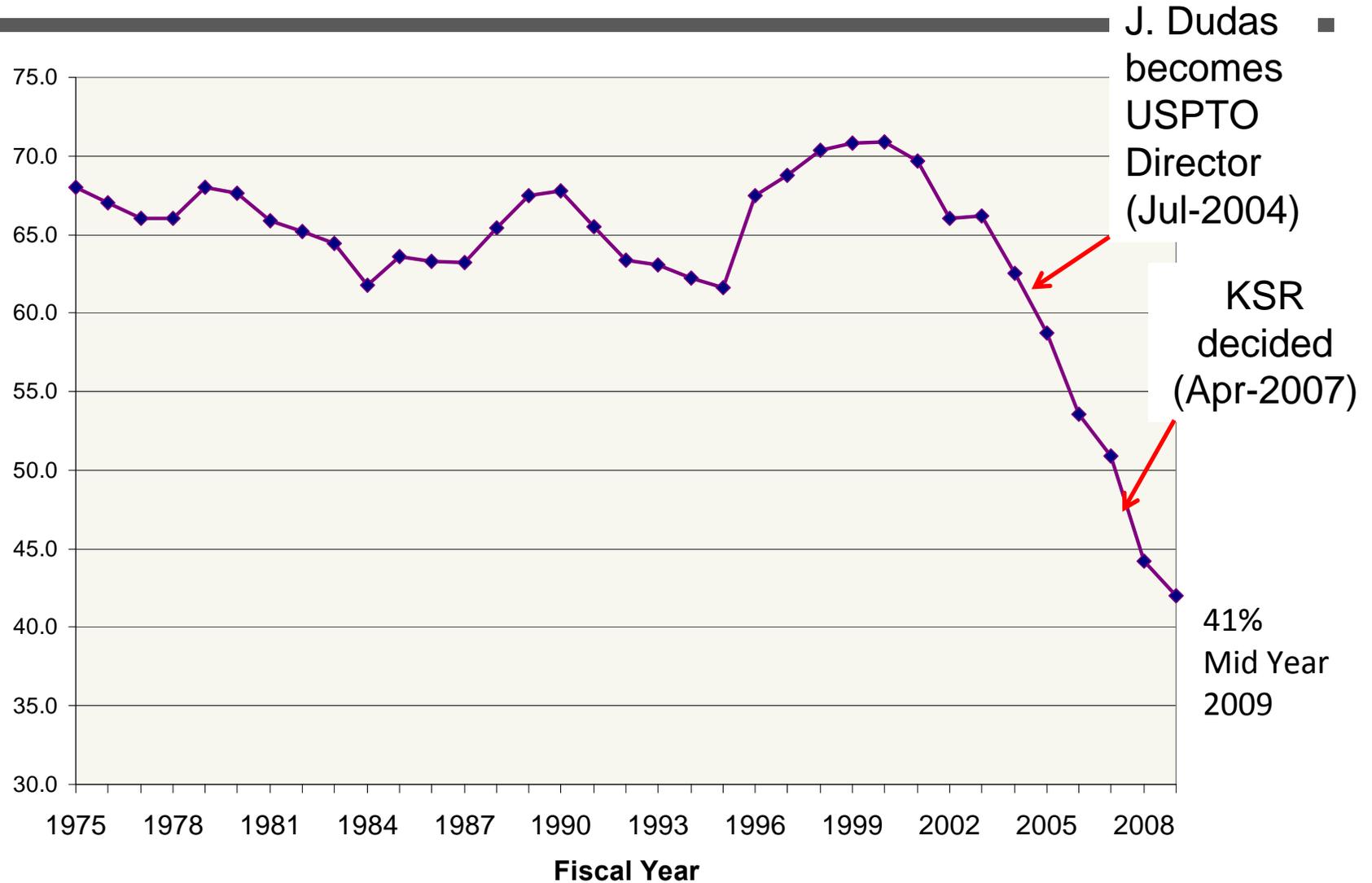
- Burden of proof
 - In the proposed cancellation proceedings, there is no presumption of validity and the burden of proof is by preponderance of evidence
 - During litigation, the patent is presumed valid and the burden of proof is by clear and convincing evidence
- Timing issues for pharmaceutical patents
 - Because of 12 month deadline to file petition, challenges to patents using the cancellation proceeding will occur much earlier than infringement actions
 - Patent can issue before product is approved by FDA and before sales figures are known
 - Generics might not pursue this cancellation option because they might not know whether they will make a generic version of patented product

Implications of undergoing cancellation proceedings

- Stay
 - Because the USPTO can stay the cancellation proceeding if a “pending civil action addresses the same or substantially the same questions of patentability raised against the patent,” patent owner could potentially take patentability decision out of the USPTO hands if the same issues are pending in civil litigation

Obviousness and *KSR* as major factors in rejection of applications

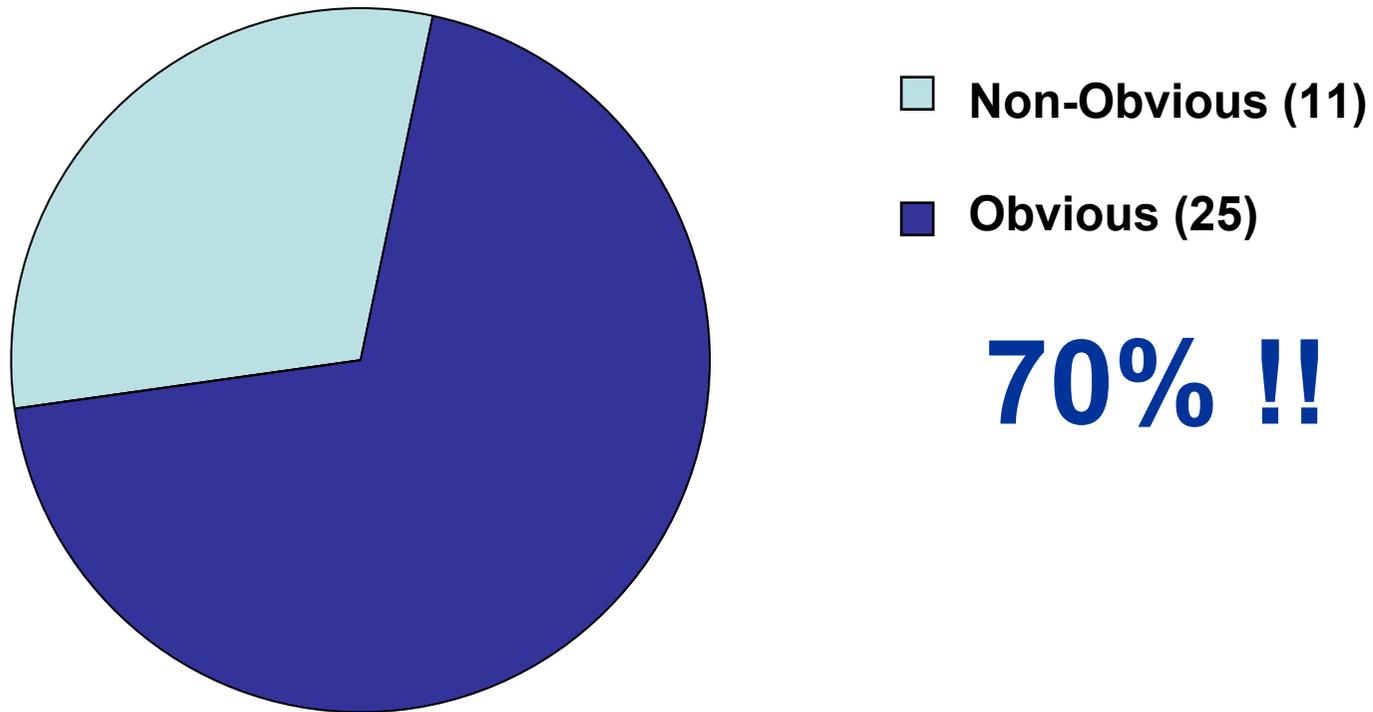
USPTO Allowance Rate



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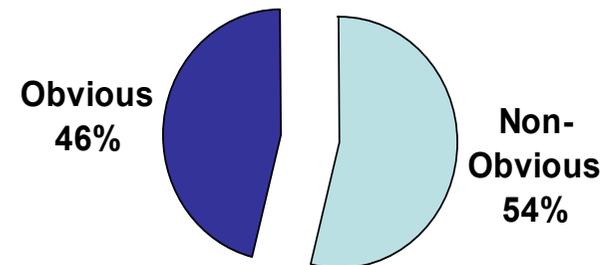
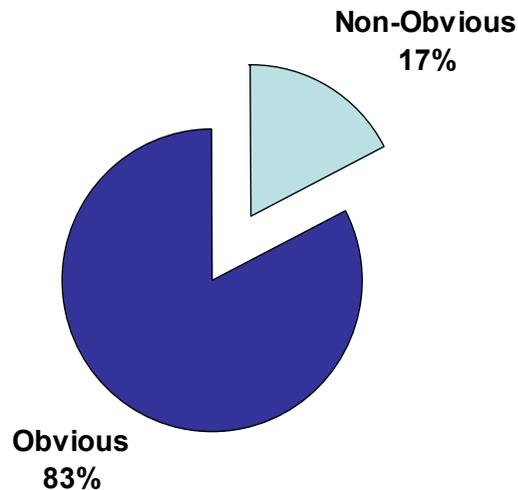
Federal Circuit After *KSR*

- 36 decisions on obviousness since *KSR*



Federal Circuit Statistics

- 23 electrical/mechanical
 - 4 non-obvious (17%)
 - 19 obvious (83%)
- 13 chemical/biopharm
 - 7 non-obvious (54%)
 - 6 obvious (46%)

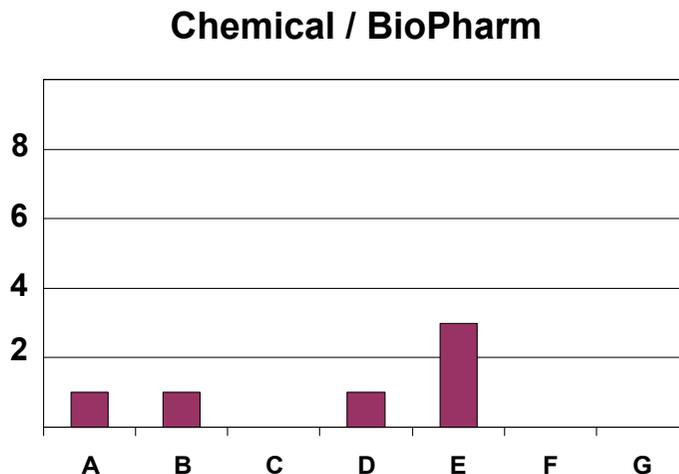
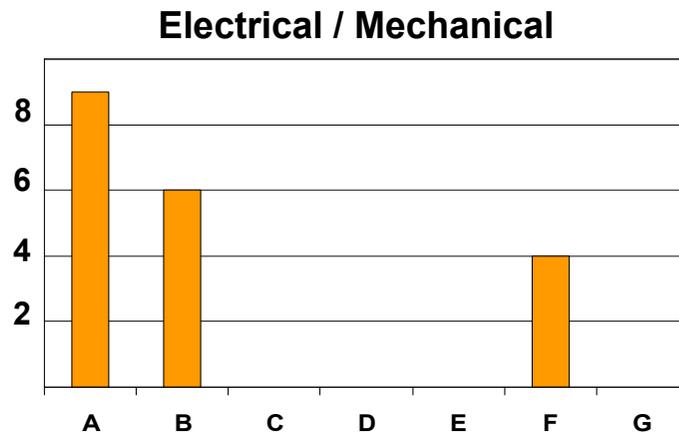


USPTO KSR SEVEN GUIDELINES

- A. Combining prior art elements according to known methods to yield **predictable** results.
- B. Simple substitution of one known element for another to obtain **predictable** results.
- C. Use of known technique to improve similar devices in same way to achieve **predictable** result (“base” device or method and “comparable” device or method in the prior art).
- D. Applying a known technique to a known device ready for improvement to yield **predictable** results. (“base” device and known technique).
- E. “Obvious to try”—choosing from a finite number of identified, **predictable** solutions to known problem, with a reasonable expectation of success.
- F. Known work in one field may prompt variations of it for use in same or different field based on design incentives or market forces if the variations would have been **predictable** (KSR—mechanical pedal upgraded with sensor)
- G. T-S-M test (Teaching-Suggestion-Motivation) coupled with **expectation of success**.

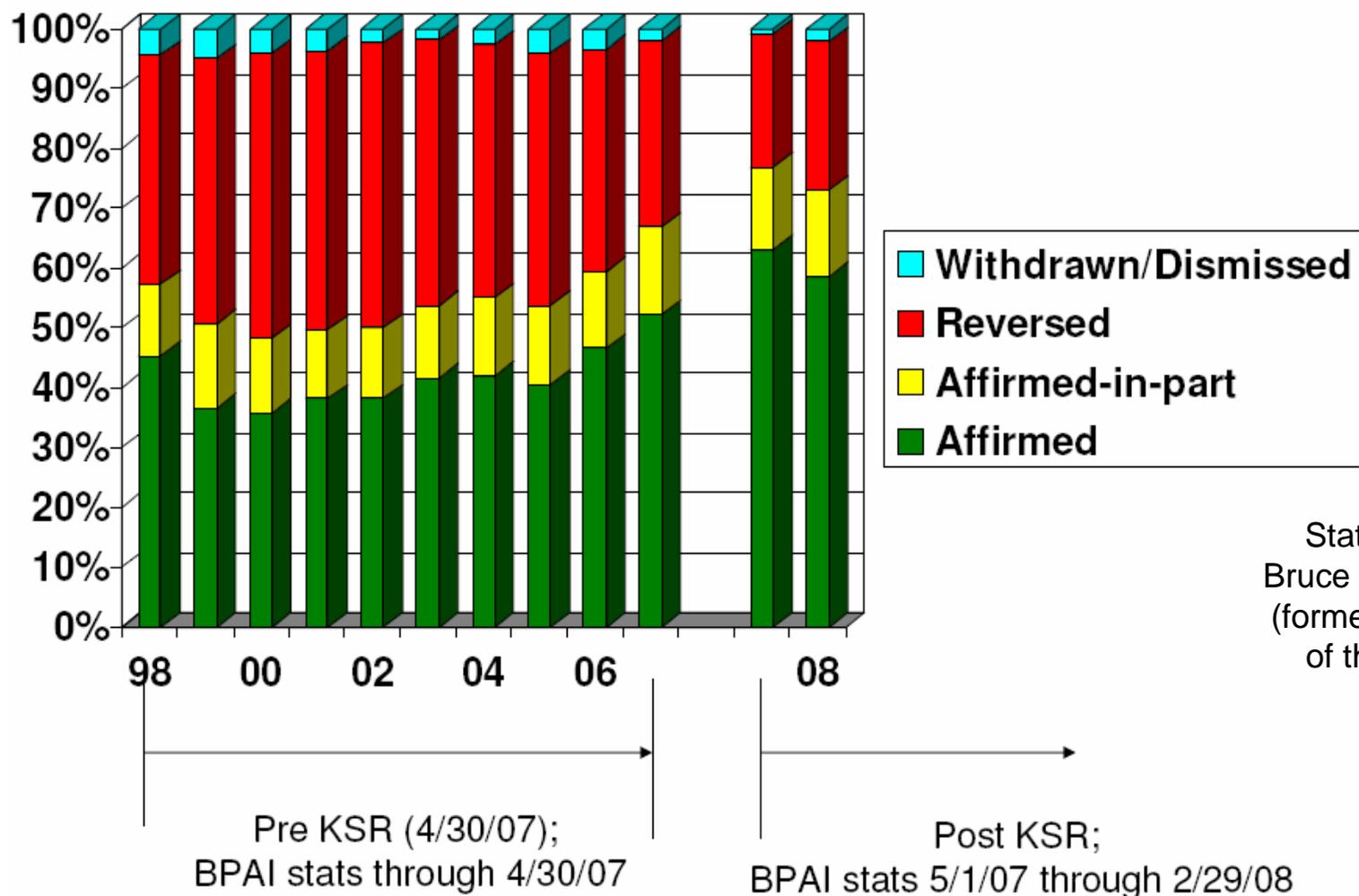
Federal Circuit Statistics

- Breakdown of obviousness rationales by technology



- A. Combining prior art elements according to known methods to yield **predictable** results
- B. Simple substitution of one known element for another to obtain **predictable** results
- C. Use of known technique to improve similar devices in same way to achieve **predictable** result
- D. Applying a known technique to a known device ready for improvement to yield **predictable** results
- E. “Obvious to try”—choosing from a finite number of identified, **predictable** solutions, with a reasonable expectation of success
- F. Known work in one field may prompt variations of it for use in same or different field based on design incentives or market forces if the variations would have been **predictable**
- G. TSM test

USPTO Board – Post-KSR Statistics



Conclusions from Statistics

- Decisions by the Federal Circuit appear to favor different approaches to finding obviousness depending on the subject matter of the application
 - Electrical/mechanical—Favor combining or substituting known elements, or transferring known work from one field to another
 - Chemical/biopharm—Favor using obvious to try and to a lesser extent combining or substituting known elements,
- Almost universal argument against obviousness rejections is the lack of **predictable** results and lack of a reasonable expectation of successfully producing the claimed invention via the proposed combination

Effects of KSR in Examination

- KSR (and PTO guidelines and MPEP) have embolden examiners to assert prima facie case
- Examiners push prima facie case more and some demand data and declarations
- Even supervisors are less inclined to allow application if there is a borderline case of obviousness
- No real change to rebutting prima facie case

NEW USPTO Director Kappos on KSR

“Inventors and practitioners will need to take these developments [Federal Circuit obviousness decisions] into account when preparing and prosecuting applications. For example, it may be necessary to review a broader cross-section of prior art than was previously necessary, or to consider filing evidence of unexpected results earlier rather than later in the course of prosecution. **By being proactive, practitioners will expedite prosecution and avoid unnecessary fees and RCE filings.**”

From Director Kappos’s Blog, entry of 24-Nov-2009, at <http://www.uspto.gov/blog/> visited on 24-Nov-2009

Light at the end of the tunnel?

NEW USPTO Director Kappos

Aug 25, 2009

- **"Patent quality equals granting those claims the applicant is entitled to under our laws."**
- "On the subject of quality, there has been speculation in the IP community that examiners are being encouraged to reject applications because a lower allowance rate equals higher quality. Let's be clear: **patent quality does not equal rejection.**"

STRATEGIES FOR PROSECUTION

- Original application
 - Genus
 - Subgenus
 - Species
 - *Not selection invention.*
- Secondary applications
 - Formulations
 - Combinations
 - Salts
 - Isomers
 - Dosages
 - New uses of old products



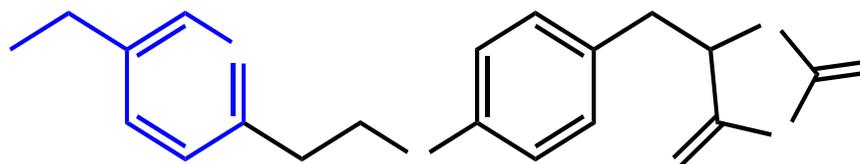
STRATEGIES FOR NEW MOLECULES

- Under *KSR*, and recent case law, there must be some reason for a chemist to modify a known compound in a particular manner
 - Start with an identification of a “lead compound”
 - Consider “structural similarities and differences”
 - Consider motivation and likelihood of success
- Motivation to modify “can come from any number of sources” but “it still remains necessary to identify some reason” to make the modification
 - No motivation because structure did not predict function
 - No motivation because the modification was not “routine”

Takeda: Modify Chemical Structure

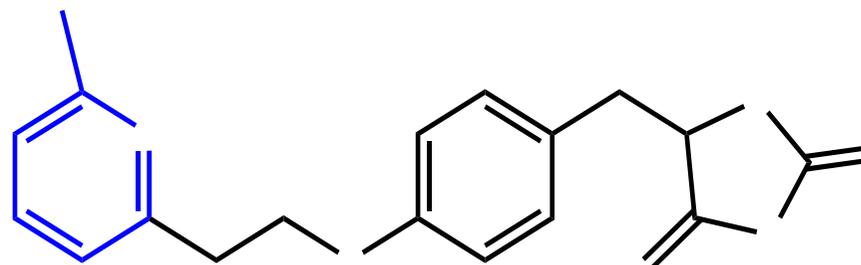
- ACTOS[®] (pioglitazone) for Type II diabetes

- Claimed Compound:



- Obviousness Contention

- Prior Art “compound b”



- Modify with 2 changes:

- homologate the methyl group, and
 - ring walk the group

Takeda: Not Obvious

- “It remains necessary to **identify some reason** that would have led a chemist **to modify a known compound** in a particular manner to establish prima facie obvious of a new compound.”
 - Reason to make changes necessary to achieve claimed compound
- Takeda was able to articulate a good story for how the invention came to be

Eisai: Not Obvious

- Decided after *Takeda*
- “[P]ost-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound.”
 - Need to explain why and how to chose a lead compound

NEW MOLECULE APPLICATIONS: GENUS

Arguing no prima facie case of obviousness:

- Lead compound?
- No reasonable expectation of success.
 - Argue lack of predictability (i.e. structure not “predictable”).
- Teaching away — Read prior art applied for evidence of teaching away.
- Prior art (including file history) may support lack of predictability argument(s).
- Consider level of ordinary skill in art evidence: Remember duty of candor. (Rule 56 declarations)
- Consider arguing missing claim limitations.
- If works for genus, works for dependent claims directed to subgenus and species.
- See, MPEP 2142-2144.04
- Advocate no need to show surprising or unexpected properties because properties are irrelevant if no PFO established.

Secondary Patents

Pfizer: Salt of Known Compound (Pre-KSR)

- Product:
 - NORVASC® for hypertension
- Claim:
 - Amlodipine besylate salt and related compositions
- Prior Art I:
 - Amlodipine and other pharmaceutically acceptable salts
- Prior Art II:
 - 53 pharmaceutically acceptable salts known

Pfizer: Obvious

- Reason to combine need not be expressly taught
 - Reason to modify ‘may be found in any number of sources, including ***common knowledge***, the prior art as a whole, or the nature of the problem itself.’”
 - One of ordinary skill would have been motivated by the ***problem itself*** to choose a salt structure different from the prior art because the prior art salts had problems
 - ***Reasonable expectation of success*** was based on probability that at least one of 53 possible salts would be acceptable, even though it was impossible to predict whether any individual salt would work

Aventis: Purified API (Post-KSR)

- Drug:
 - Altace[®] (ramipril) for high blood pressure
- Claim:
 - Formulation of ramipril “substantially free of other isomers” (5(S) configuration alone)
- Prior Art 1:
 - 5(S) + SSSSR
- Prior Art 2:
 - Suggestion 5(S) was potent part of mixture

Aventis: Obvious

- If desirable property comes from one component, prima facie obvious “even without an explicit teaching that the ingredient should be concentrated or purified.”
- Increased potency was expected result
- No evidence that separating 5(S) from SSSSR was outside the capability of a skilled artisan

What can we do?

Tell The Story Of The Invention...



OK, DAD. I'LL JUST STAY HERE QUIETLY GROWING UP AT AN UNBELIEVABLE RATE, NEVER SPENDING MUCH SPECIAL TIME WITH MY OWN DAD, WHO'S ALWAYS WORKING.



Tell the story of the invention

- *Forest Labs Inc. v. Ivax Pharm. Inc. (Post KSR)*
 - FC: enantiomerically pure citalopram was not obvious over the racemate; known purification methods available at the time of the invention to resolve the racemate, circa 1989, were themselves non-obvious
 - Showed unexpected results of isolate isomer
- *Sanofi-Synthelabo Inc. v. Apotex Inc. (Post KSR)*
 - FC: enantiomerically pure clopidogrel was nonobvious over its racemate
 - Experts testified that it was impossible to predict the degree by which enantiomers would differ in terms of biological activity and toxicity
 - Experts further testified that it was rare and unexpected for the biological activity of a racemate to rest solely in one enantiomer, and toxicity in the other, as was the case for clopidogrel
 - Successful resolution of the clopidogrel racemate was unpredictable and non-obvious

NON-NEW MOLECULE APPLICATIONS POST-KSR

Key is to establish no finite number of predictable solutions with anticipated success.

- **Salts, Isomers, Dosage, Pharmaco-Kinetic Applications, Formulations, Combination Therapies, Methods of Making – may be more difficult.**
 - What to do? Compelling story of blood, sweat, tears in finding solution to unpredictable problem, i.e. not predictable solutions.
 - Story in spec? declaration? or oral? Consider interview.
 - o If take expert to interview, prepare thoroughly.
 - o Remember Rule 56 duty of candor and best mode.
- **Polymorphs – do not seem to be more difficult.**
 - U.S. PTO tends to accept the magical nonobviousness of polymorphs.
- **Indications - depend on facts**
 - No more difficult after KSR if indication is first indication and presented in new molecule case.
 - May be more difficult after KSR if additional indication where the prior art is the new molecule case and the additional indication is disclosed in laundry list.

Strategies for Secondary Patents

Rebutting *prima facie* case of obviousness:

- Consider submitting comparative data—i.e. determine closest prior art, and compare against it.
- Unexpected results (property or result not “predictable.”)
- Unpredictability commensurate in scope.
 - Consider interview with examiner to agree on testing compounds.
- Commercial success: commensurate in scope and nexus with the claimed invention.
- Watch out for duty of candor (Rule 56); Danger: inconsistent, non-disclosed data.
- For subgenus/species.
 - Commercial success may be easier, particularly for species.
 - Consider claiming polymorphs, isomers, solvates, salts.
 - Nexus: was success because of marketing?

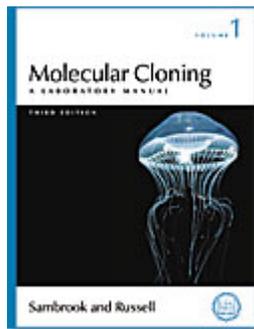
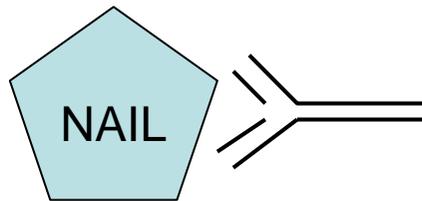
SELECTION INVENTIONS

- If parent new molecule application is prior art
 - Is there a *prima facie* case and if so, can it be rebutted?
 - Obvious to try may be more prevalent.
 - Bottom line: are there signposts that lead you to selection of a smaller group from a much larger cited art group?
 - If you cannot attack *prima facie* case, consider rebutting as above.
 - Duty of candor (Rule 56)
 - Enablement issues
 - MPEP 2144.08-09– patentability of species over genus (size of genus, express teachings of subgenus, structural similarity, similar properties or uses)

Unpredictable Art of Biotech ?

- *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009) (April 3, 2009)
- Facts:
 - Claims:
 - An isolated nucleic acid molecule that encodes “a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO: 2, wherein the polypeptide binds CD48.”
 - SEQ ID NO: 2 is the amino acid sequence of the NAIL protein

Obviousness Rejection at the Board



A nucleic acid
encoding the
amino acid
sequence of the
NAIL protein

Obvious at the PTO and Federal Circuit

- Valiante’s disclosure of the polypeptide and method of obtaining the DNA “established Valiante’s possession of the amino acid sequence” (predictable!)
 - This provided a reasonable expectation of obtaining the DNA sequence
 - The recognition of NAIL’s important role in the immune response would have motivated a POSA “to apply conventional techniques” to isolate the DNA sequence
- Kubin used “conventional techniques” to isolate the DNA
 - Kubin argued that Sambrook was “deficient,” but the court noted Kubin’s reliance on Sambrook in the spec as providing “standard biochemical methods,” saying that Kubin could not have it both ways
 - [Beware that reliance on “standard methods” in the specification may invite reliance on that text to support an obviousness challenge]

“The record shows that the prior art teaches a protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning this gene. Therefore, the claimed invention is **“the product not of innovation but of ordinary skill and common sense.”**”

Post-KSR Strategies

- **Application drafting:**
 - Avoid “problems” in the Background
 - Emphasize complexity and unpredictability
 - Make sure ready for patenting
 - Consider strategically narrowed claims
- **Prosecution:**
 - Interview Examiner
- Hold the Examiner to requirements:
 - “There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”
- Argue against combination:
 - Not combinable by known methods
 - Elements in combination do not perform the function that each performs separately (not predictable)

POST-KSR STRATEGIES: PROSECUTION

- Unpredictability can be important: show that invention was not predictable.
 - Show no reasonable expectation of success.
 - Show there was not a “finite number of identified, predictable solutions.”
 - Show there was only general guidance
 - Show unexpected results ??
 - Other objective indicia of nonobviousness??
- Story of teaching away
- Showing lack of predictability or expectation of success may require submitting data and/or declarations earlier in prosecution; evidence to destroy, not rebut, the prima facie case.

Post-KSR Strategies

Seek reexamination of competitor patents?



General Prosecution Tips

- **Preparation starts before receiving the first Office Action**
 - Do your homework PRIOR to examination
 - Claim strategies
 - Avoiding a final office action
 - Interviews
 - Arguments in view of KSR
- Help the Office see the invention!
- How helpful is the Appeal Process?
- Using the Accelerated Prosecution Procedure

To Effectively Assist the PTO

One Must Understand the Invention

- One must understand the relative importance of the technical features of the invention
- One must understand how the invention fits within the prior art landscape
- One must recognize the weaknesses in their own case
- One must have a strategy for each invention/application
- One must account for fall back positions
- One must recognize that money spent to achieve this understanding will generally offset other prosecution costs

Help the Office See the Invention

- Do your homework PRIOR to Filing
- Should be clear you did your homework - **Specification**
 - Good Prior Art Search !!!
 - Specification clearly articulates the invention and distinguishes it over the art
 - What was the problem and how was it solved?
 - Subsequent discussions with the Examiner regarding patentability will find a basis in the specification.
 - Lay groundwork for KSR arguments
- Early work saves prosecution costs!

Help the Office See the Invention

- Should be clear you did your homework - **Claims**
 - Good Prior Art Search!
 - Claims clearly distinguish over the art & conform to US practice!
 - Claim 1 should clearly distinguish the invention over the art.
 - Claim 1 shouldn't be the broadest claim
 - » Focus the Examiner on a claim that clearly distinguishes over the art
 - Broader claims later (claim 10 or in **continuation**)!
 - » Goal: Examiner appreciates the invention

Help the Office See the Invention

- Should be clear you did your homework - **Claims**
 - Independent Claims of varying scope
 - Strong set of dependent claims
 - Add additional **patentable** features
 - Bullet claims for enforcement
- Presenting claims of varying scope avoids Final Office Actions
 - New Rejection necessitated by amendment results in Final OA
 - If element was previously claimed final OA is improper

Help the Office See the Invention

- Do your homework **PRIOR** to examination
 - Good Prior Art Search!
 - Cite references in an IDS **PRIOR** to Examination
 - GOAL: The Examiner doesn't find better prior art**
- **Prosecution**
 - Hold the Examiner to requirements so we can respond and address the concerns:
 - “There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”
 - Argue features of dependent claims so Examiner will consider these features.

More Prosecution Strategies

- Unpredictability can be important: show that invention was not predictable.
 - Show no reasonable expectation of success.
 - Show there was not a “finite number of identified, predictable solutions.”
 - Show there was only general guidance
 - Show unexpected results ??
 - Other objective indicia of nonobviousness??
- Showing lack of predictability or expectation of success may require submitting data and/or declarations earlier in prosecution; evidence to destroy, not rebut, the prima facie case.
- EARLY Examiner Interviews

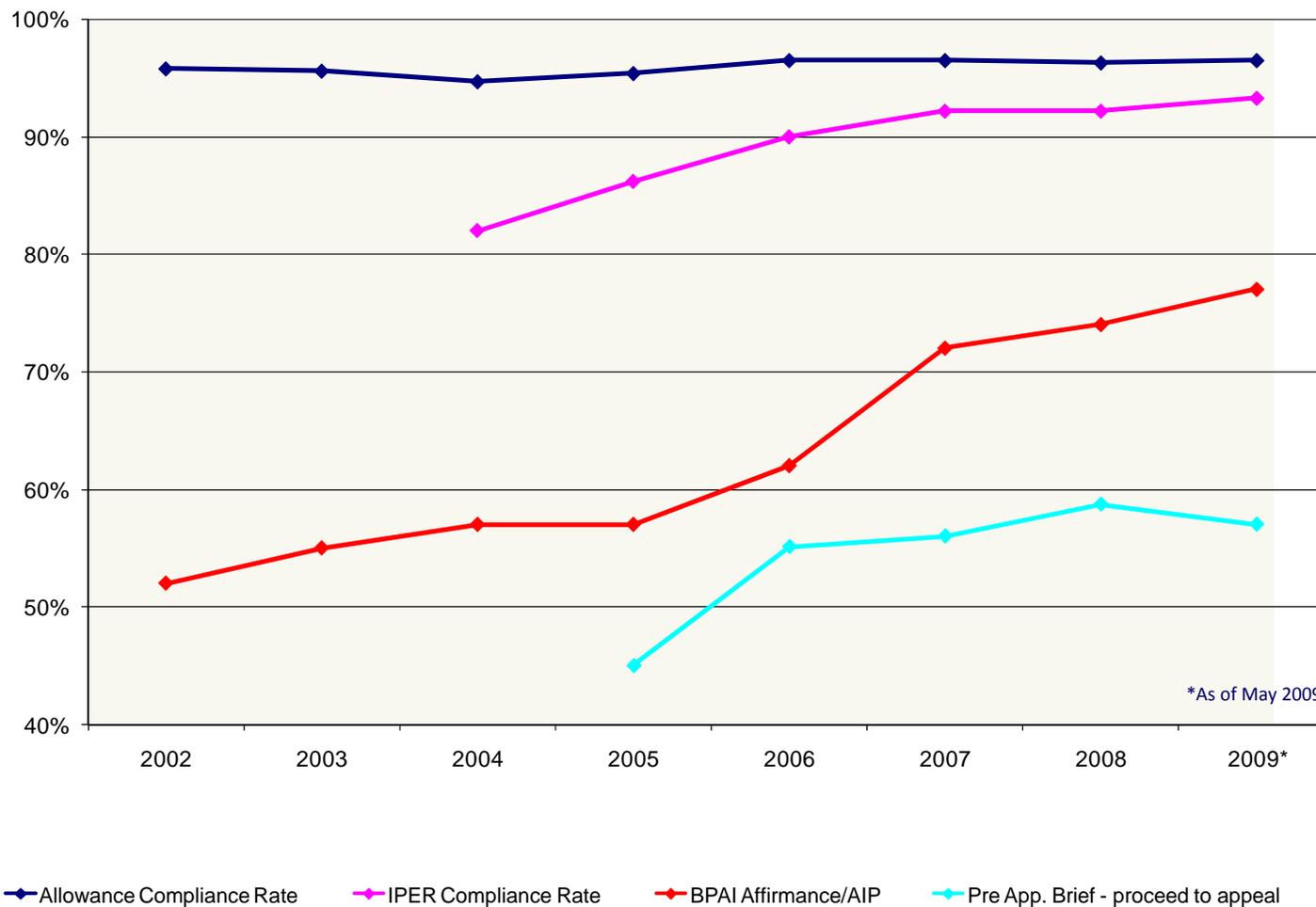
First Office Action Interview Pilot Statistics

as of May 4, 2009

- 493 Applicants have joined the pilot program
- 370 Pre-interview Communications (PFA OA) have been mailed
- 263 Interviews have been conducted
- 226 First Action Interview Office Actions have been mailed
- 84 Allowances
 - 44 allowed after pre-interview communication but before FAI office action
 - 15 allowed after the FAI office action
 - 25 allowed without/before pre-interview communication

Source: www.uspto.gov/.../ppac_2009jun18_patent_operation_update.ppt

How effective is the Appeal Process?



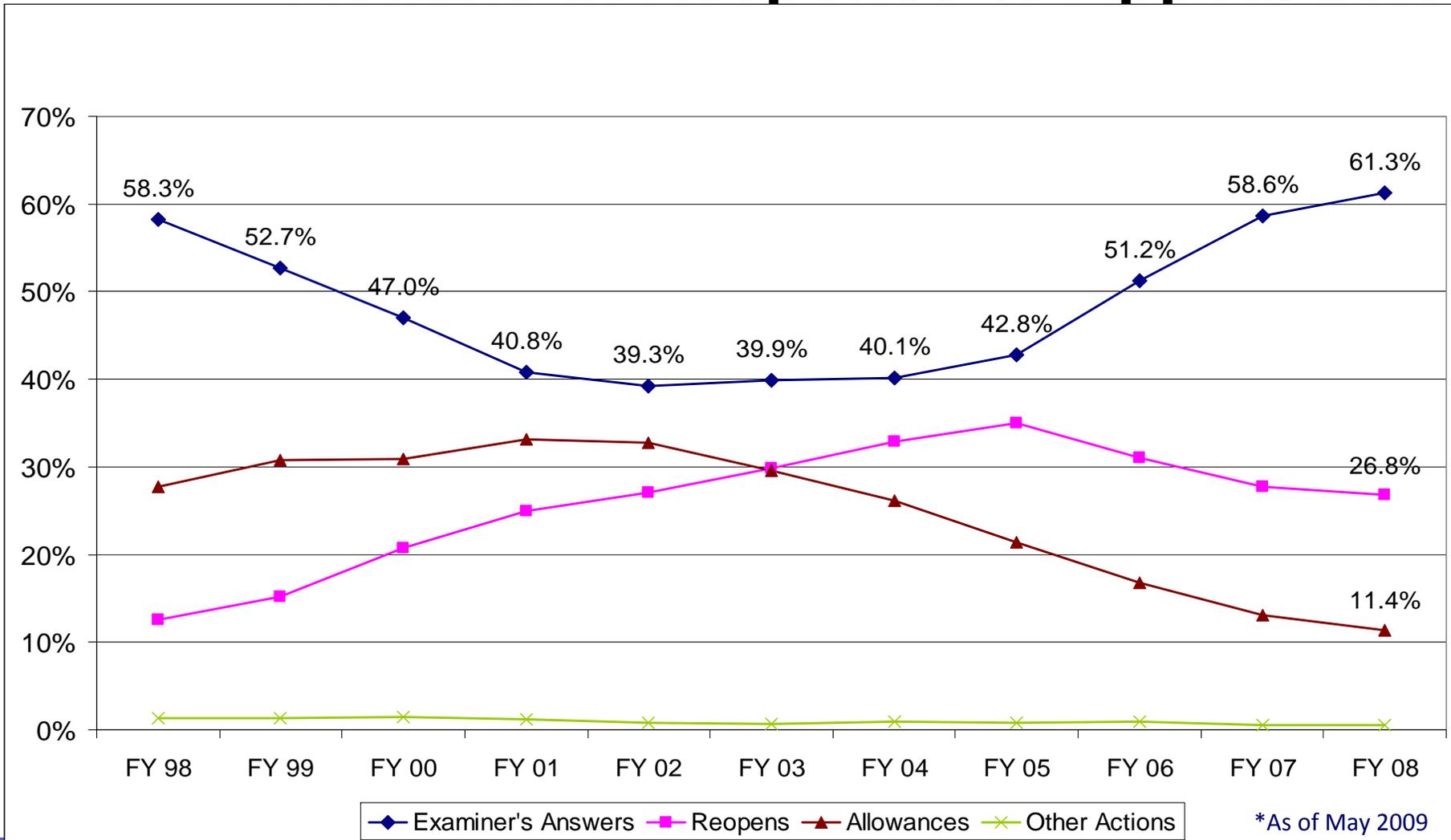
Source: www.uspto.gov/.../ppac_2009jun18_patent_operation_update.ppt

Is the Appeal Process Helpful ?

- Appeals to the Board
 - Board affirmance rate is going up
 - Proposed rule changes are onerous
- Pre-appeal brief request for review
 - Much less effective than 5 few years ago

Appeal Conference Effects

Actions in Response to Appeal Brief



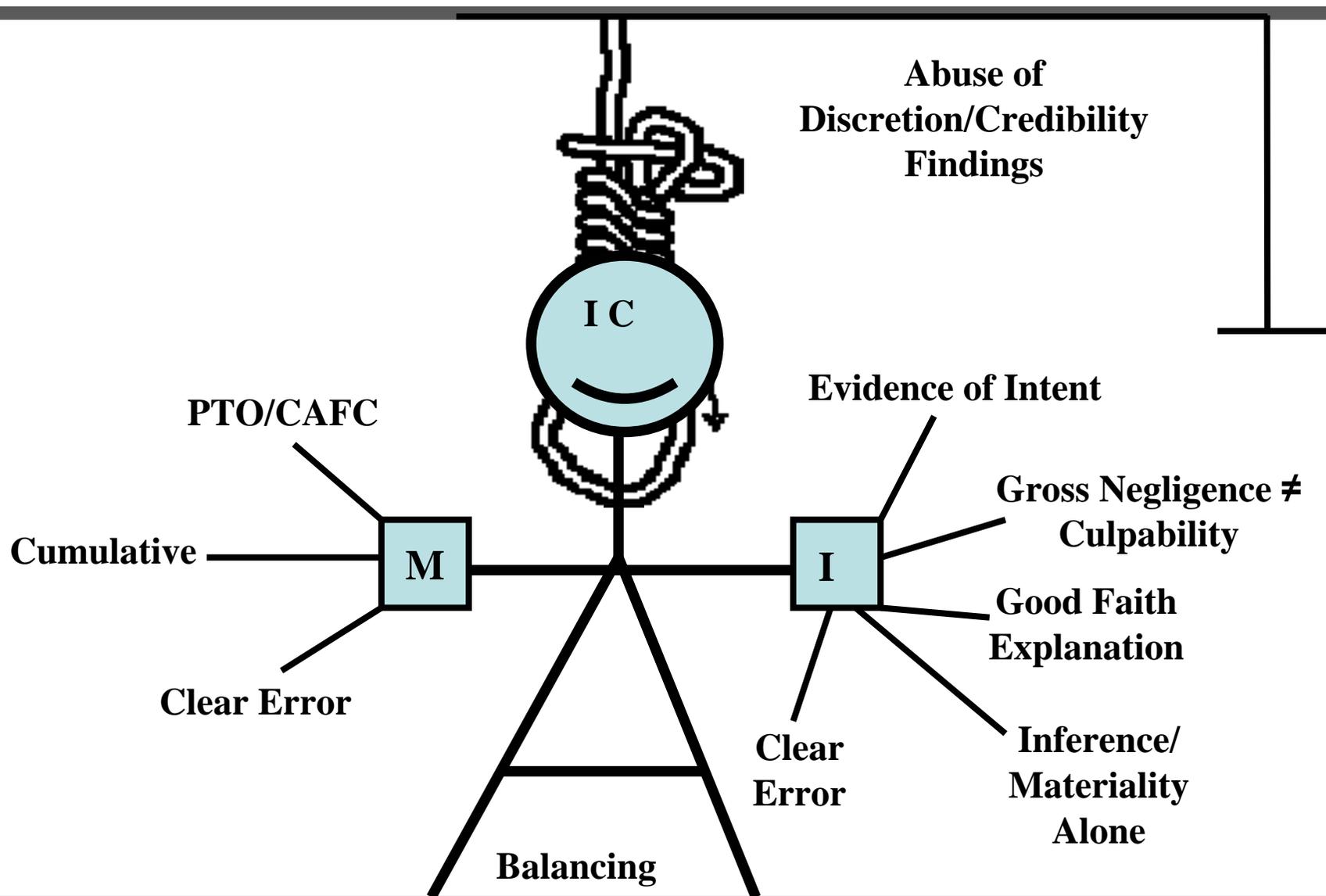
Appeal Process can be effective...

- Appeals to the Board
 - Clear misapplication of the law
 - ex – inherency
 - Important to limit the number of issues
 - Senior Examiner who digs in heels
- Pre-appeal brief request for review
 - Get more experienced examiner involved in a case with a new examiner (consider Interview instead!)

Inequitable Conduct

- What is it?
- What are its consequences
 - valid, infringed patent held completely unenforceable
- Who can be accused of it?
- How does it work?
- What are YOUR obligations, given the existence of this defense?
- What else can one do?

How Inequitable Conduct Works



Who has a Duty to Disclose? USPTO Rule 56(c)

- Each inventor named on the application
- Each attorney or agent who prepares or prosecutes the application (both U.S. and **foreign**)
- Each person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, assignee, or anyone to whom there is an obligation to assign the application
- Duty of disclosure/candor is owed to the USPTO

Allegations of Inequitable Conduct Can Stem From . . .

- **Failure to disclose references or other external information to the Examiner**
 - References **known** to person with duty of candor were not submitted (e.g. *Molins*)
 - Documents from co-pending, related litigations (*Critikon*)
 - Office actions and references from co-pending, related U.S. patent applications (*Dayco, McKesson*)
- **Inaccurate or imprecise arguments or data in the application text or submitted by applicant during prosecution**
 - Statements or data in the application text are not supported by the facts (*Hoffman La Roche v Promega*)
 - Examples or experiments were not performed but application suggests that they were performed (*Bayer v. Housey*)
 - Prophetic examples – present tense
 - Information inconsistent with attorney arguments is not disclosed (*Cargill v Canbra Foods*)
- **Declarations to support patentability**
 - Arguments or data inconsistent with overall facts (*Pharmacia v Par*)
 - Data or information not included in declaration (*Aventis v Amphastar*)
 - Declarant has a possible bias in favor of applicant that is not disclosed (*Ferring, Nilssen*)
 - E.g. financial ties to the applicant
- **Other actions taken during drafting or prosecution:**
 - Naming incorrect inventors
 - E.g. allegedly to prevent another party from having an ownership interest
 - Failing to disclose the best mode in the application
 - E.g. allegedly to prevent disclosure of an important trade secret
 - Improperly paying small entity fees and failing to correct (*Ulead*)
 - Obligation to license to large entity (*Nilssen*)

Considerations for Disclosure

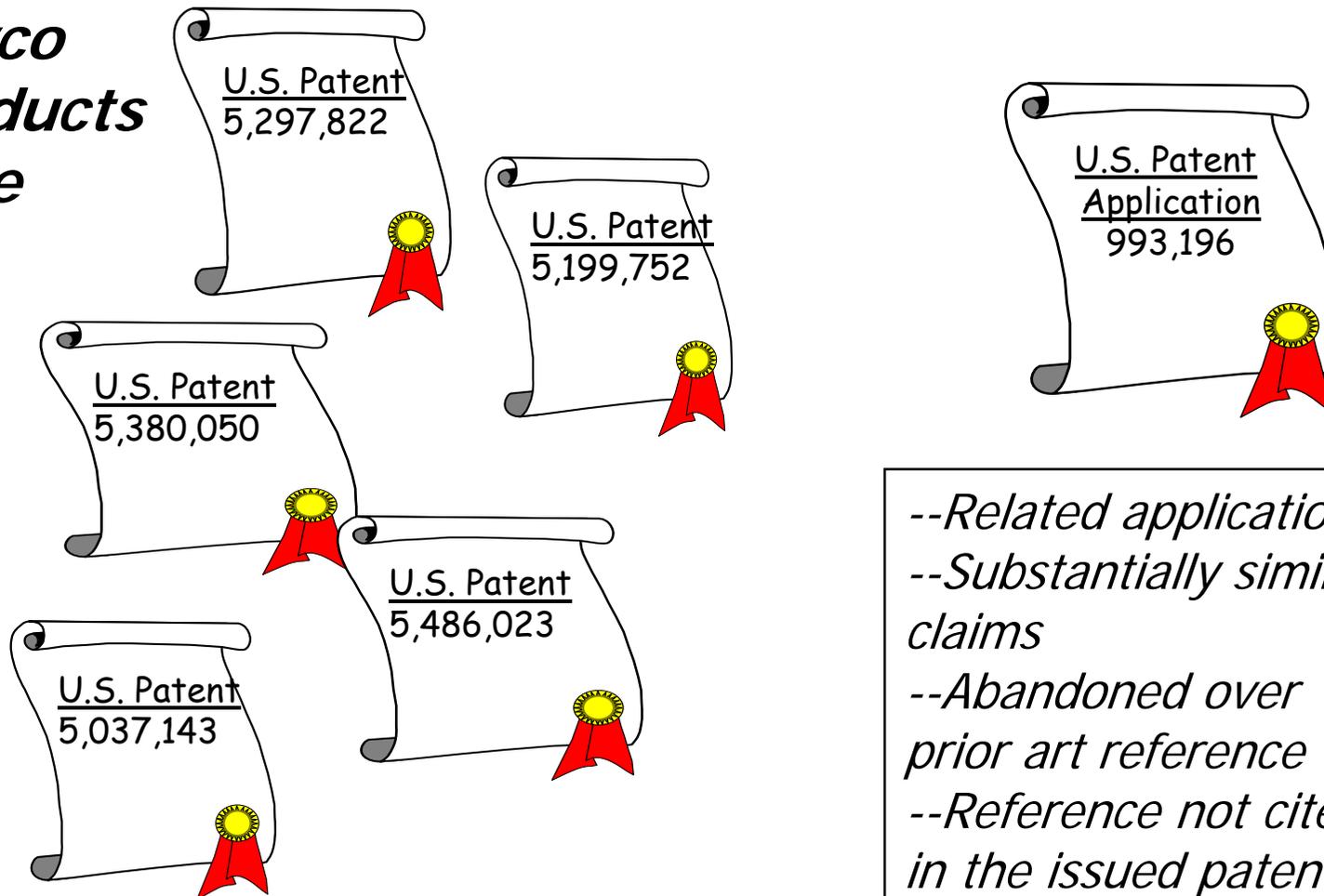
- Search reports (documents only or search results)
- References authored by inventors or from applicant
- References cited in the application text
- Prior products sold or used in the United States
- Related patent applications and litigation proceedings
- Confidential prior art (internal prior art)
- References not in English

Not sure if information is material?

Federal Circuit advice: DISCLOSE IT and let the Examiner decide

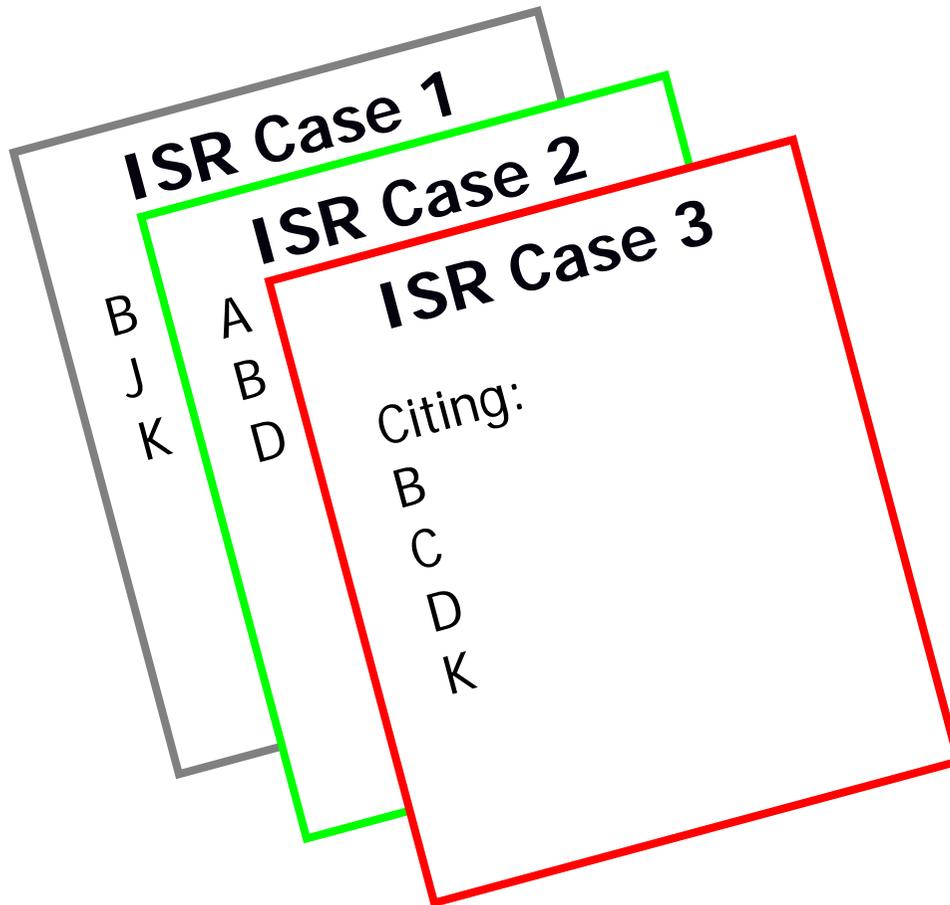
Example - Co-Pending U.S. Applications

Dayco Products Case



--Related application
--Substantially similar
claims
--Abandoned over
prior art reference
--Reference not cited
in the issued patents

Example – Co-Pending, Related Applications



- Overlapping inventors
- Overlapping application disclosures
- Similar claims
- Family members (same priority chain)

Example – Non-English References

- Methods of submission:
 - Include complete translation
 - Other options
 - “Concise statement of relevance”
 - English-language family member, e.g. if document is a patent or published application
 - Partial translation (of the relevant information)
 - English-language abstract
 - Point Examiner to location in application text where document is discussed
 - Copy of search report listing document, if search report is in English

Related Co-Pending Litigations

- U.S. litigation papers
 - “Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office.” M.P.E.P. § 2001.06(c).
 - Often arises in reissues and reexaminations
- What about EPO oppositions or other non-U.S. proceedings?

Thank You!



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