

# AIA, Business, Practice, and Beyond

## Examples of IP Relevance – Patents

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- ▼ Acquisition of another company
- ▼ Licensing of a portfolio
- ▼ Importation of product into US
- ▼ Bankruptcy

# Due Diligence

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Generally hire independent counsel to evaluate:

- Freedom to operate
- Strength of patent position
  - ✓ Scope
  - ✓ Coverage of product
  - ✓ Ownership
  - ✓ Controversy re: inventorship?

# Freedom to Operate

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- Third Party positions
- Search Done?
- Opinions rendered?
- Suits threatened?
- Consider timeline for products – will patents expire?

# Strength of Position:

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- ▼ Claims issued or pending?
- ▼ Narrow “picture” claims focused on product?
- ▼ Broader claims to avoid “design around”
  - varies by industry
- ▼ Platform technology

# Example

2002 – Platform technology

Formulate combinations of antineoplastic drugs

- 1) so they are in a synergistic ratio;
- 2) Maintain the synergistic ration when administered.

(done by designing liposome or other carriers to control release)

2005 – Specify drug combination in specific ratio in specified liposomes

A composition for parental administration to a subject which composition comprises liposomes having associated therewith daunorubicin and cytarabine, and wherein

- (a) the daunorubicin and cytarabine are co-encapsulated;
- (b) the administered ratio is maintained in the blood for at least four hours after administration to the subject;
- (c) the daunorubicin:cytarabine mole ratio is about 1:5;
- (d) the liposomes have a mean diameter of less than 250 nm;
- (e) the composition comprises no therapeutic agents in addition to the daunorubicin and cytarabine; and
- (f) the liposomes comprise DSPC, DSPG and cholesterol in a mole ratio of about 7:2:1.

# Checklist Items

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Ownership – Assignments documented/recorded



Inventorship – Important in US  
– Contention within same organization?  
– Contention with differing obligations?  
– CREATE act

# How to Market IP

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“Recent” line of cases allowing DJ actions

Two cases in 2007

- *MedImmune v. Genentech*

No actual threat of suit needed.

- *SanDisk v. StMicroelectronics*

avoiding threatening to sue not enough

- *PowerTech v. Tessera* (2010)

license situation is ripe

# Solutions/Options

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- Do not explain why a license is needed
- Bring suit before sending a demand letter
- General press release?
- May lack personal jurisdiction
- Consult a lawyer – but we are guessing too.

# Additional Solutions / Options

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- A Confidentiality Agreement with the Prospective Licensee may Help
  - Provide that all communications between the parties, including written correspondence, can be used only for the licensing negotiation and no other purposes (*SanDisk*)
- The Demeanor During Negotiations can Reduce the Risk of Litigation
  - Avoid using threats
  - Ensure commercial reasonableness of offer
- Get to the Prospective Licensees Early – Before or at an Early Stage of Infringement – Can Reduce the Risk of Litigation

# Suggestions for Negotiations and Future Litigation

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- Once started, the negotiations need to proceed vigorously to preserve patent rights
- If all else fails, consider “file but not serve” strategy
- Recent decisions allow consideration of prior settlements as evidence of a reasonable royalty damages calculation

# Negotiations: Role of IP Position

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Valuation of IP operate to be licensed.



But risk factors weigh in



FTO



Stage of development



competitors

Timeline – evergreening possibilities

## Open Issues

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- Liability for infringement – joint infringement
  - *Akamai Tech v. Limelight Networks*
  - *McKesson Tech v. Epic Systems*
- *En banc* Fed. Circuit hearings held – decisions due

**BUT LOOK AT THE CLAIMS  
DRAFTED FOR YOU.**

- Patentable Ideas?
  - *Mayo v. Prometheus* before the Supreme Court

# Overview AIA

## Pre issuance changes

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First inventor to file (Applicable to applications with effective filing dates 16 March 2013 or later.)

Prior art definition (Applicable to applications with effective filing dates 16 March 2013 or later.)

Interference vs. Derivation proceedings (Applicable to applications with effective filing dates 16 March 2013 or later.)

Third party participation (Available 16 Sept. 2012 with respect to any application.)

(Best mode – still a requirement but not a defense in actions filed on or after 16 Sept. 2011.)

# Post Issuance Changes (or not) before the PTO

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For the patentee or third party: *Ex parte* reexam – no change

For the patentee: Supplemental Exam (Available on or after 16 Sept. 2012 for any patent)

For third parties: Post grant review (Available on or after 16 Sept. 2012 for patent with effective filing date on or after 16 March 2013)

*Inter partes* review (Available on or after 16 Sept. 2012 for any patent)

## Phased Out

*Inter partes* reexam (Available until 16 Sept. 2012 for any patent filed after 29 November 1999)

# First to File Changes: Prior Art

Applications filed Before vs. After 16 March 2013

(Not continuations or divisionals, but possibly CIP's)

Some changes due to first-to-file

Before	After
printed publication anywhere	printed publication anywhere
Public use and sale in <u>U.S.</u>	Public use or sale anywhere; otherwise publicly available
patent or published U.S.† application naming another inventor with earlier filing date	patent or published U.S.* application naming another inventor with earlier filing date

\*Not  
Removable.  
†Removable

# Another Consequence of First-to-File

Statutory Bar	Grace Period
Before	After
Could “swear behind” publication of another < 1 year before filing	➤ disclosure “by inventor” or derived from inventor < 1 year before filing
	➤ where by another but preceded by publication of inventor
	➤ patent or publication has earlier date, but inventor pre-published or
	➤ is co-owned (including Joint Research Agreements) (if disclosed in a patent application, not journal)

# International Aspects

Before	After
“102e” date but no publication (could swear behind) > 1 year	■ earliest priority date regardless* of country (cannot swear behind)
■ earliest priority date of U.S. filing — <i>e.g.</i> , provisional	
■ after 1999 PCT filing date even if based on non-U.S. and in English	

\*CAVEAT — have to be entitled to it.

# Changes (and Constants) to Business Practice & IP Strategy

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- 1) Non-U.S. sales or use not immunized as prior art.  
(includes secret processes)
- 2) No need to file U.S. provisionals
- 3) Formalize collaborations — not really changed
- 4) Keep records (derivation)
- 5) File early and often or publish, then file.

But really applies only to new effective filing dates after  
15 March 2013.

File before then if changes are a problem.

# Ability to Influence Prosecution

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- Section 122 – Publication of Applications –  
effective for applications filed after  
15 September 2012.
- Submit printed publications and explain relevance  
including patents/applications
  - Before notice of allowance – too late if after
  - Before 6 months elapses after publication
    - But ok if, before first Office action on the  
merits

# Practices Mandated

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- Keep up surveillance of competitors' patent publications and activities
- Determine possible effect to see if worthy of search, etc.
- Works for post grant, also

# Best Mode

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Effective for any litigation filed after  
15 September 2011

- Remains a requirement
- Does not come up anymore in post-grant procedures
  - ☛ Litigation
  - ☛ Post-grant review
- Consequences of failure: Inequitable conduct?  
Discipline?


# Best Mode

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- Before the AIA:
  - An allegation that a patent was invalid for “failure to disclose best mode” was an available defense to patent infringement
- After the AIA:
  - “Failure to disclose best mode” no longer a basis for invalidity or unenforceability, either during litigation or as basis for initiating post-grant review
  - Reduces impact of a subjective and U.S.-specific requirement
  - Section 112 “best mode” requirement remains intact for prosecution (to encourage full disclosure), but penalty for failing to comply is unclear

# Post Grant Procedures for the Patentee

(In this case, also third party or U.S. PTO – no changes)

- *Ex parte* reexamination — no change except fee \$2,520  \$17,750 PTO will keep \$4,320 if refused.
  - no time limit
  - prior art only
  - substantial new question of patentability
  - preponderance of evidence
  - examiners in central reexam unit (CRU)
  - Appeal to Board & Fed. Cir. available to patentee only
  - no estoppel effect.

Not clear this could fix inequitable conduct.

# Patentee Supplemental Examination

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Available for all Patents as of 16 September 2012 – no time limit

- Opportunity to wipe out “inequitable conduct,” based on whatever is submitted – not limited to printed publications and patents
- But not fraud
- Doesn’t work with respect to allegations already raised in ANDA, infringement or ITC suits or to suits already filed unless already completed.
- Can include issues other than prior art
- Substantial New Question of Patentability
- Proposed fee \$5,180 (if reexam is ordered – \$16,120)

# Post Grant Procedures for Third Parties

- *Ex parte* reexam — as before — limited participation — only request and response to patent owner statement.
- *Inter partes* reexam until 16 Sept. 2012  
*Inter partes* review after that — must be done after post-grant review period expires — *i.e.*, after 9 months from issue

Reexam	Review
Prior art only	
Substantial New Question of* Patentability	Reasonable Likelihood will prevail
CRU	PTAB
Anytime	<u>After</u> 9 months elapsed from issue or conclusion of post grant review
Patents with effective filing dates after 29 November 1999	Any patent

\*For reexam's filed between 16 Sept. 2011 and 16 Sept. 2012 changes.

## Third Parties – As of now

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- Original statutory provisions will continue to be applicable for *inter partes* reexamination requests filed before AIA becomes effective.
- About 1000 pending *inter partes* reexamination according to PTO as of June 30, 2011:

### Inter Partes Reexamination Filing Data — June 30, 2011

Total requests filed since start of *inter partes* reexam on 11-29/99      1286

Total *inter partes* reexamination certificates issued (1999 — present)      278

# Third Parties Post-Grant Review — Totally New

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Must be filed within 9 months of issue or reissue

Any grounds may be raised 102, 103, 112, etc.

More likely than not petitioner will prevail

PTAB

Decision within 1 year

Both petitioner and patent owner can appeal

Only available for patents issued on applications  
with effective filing dates after 3/15/13

# Timing Quirks

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Post grant review

- 1) within 9 months after issue
- 2) applicable only to patents issued on applications that contain at least one claim under the first-to-file – *i.e.*, 16 March 2013 (continuations don't count)

*Inter partes* reexam

- 1) any time
- 2) applicable only to patents issued on applications filed after 29 November 1999. (includes continuations and divisionals)

*Inter partes* review

- 1) after 9 months post issue and within 1 year of any infringement suit
- 2) any patent existing on or after 16 Sept. 2012.

# Long Term

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## Up to nine months after issue

- Can challenge on any ground.

## After nine months from issue

- Printed prior art only.

# Implications

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- 1) To prevent post grant review – do not file a CIP with new claim.
- 2) Patent trolls now pay more for patents immune from *inter partes* reexam.
- 3) Patents eligible for *inter partes* reexam that issue after 16 Dec. 2011 – may want to do *inter partes* reexam before 16 Sept. 2012 to avoid X-months delay to file *inter partes* review.  
(*Ex parte* still available)

# More Details

## Post-grant Review: Petition

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- Scope: On “any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim).”
- Threshold:
  - “more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” *Compare to inter partes* review with “reasonable likelihood” of prevailing.  
or
  - “raises a novel or unsettled legal question that is important to other patents or patent applications.”

# Post-grant Review: Procedure

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- Like *inter partes* review, conducted by PTAB with one-year statutory deadline for “final determination.”
- Some differences from *inter partes* review, e.g., discovery:
  - Post-grant review: “such discovery shall be limited to evidence directly related to factual assertions advanced by either party.”
  - *Inter partes* review: “such discovery shall be limited to (A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice.”

# Post-Grant Review: Final Decision

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- PTAB “shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added[.]”
- Any party dissatisfied with the final written decision can appeal to the CAFC.
- Post-grant review may outpace contemporaneously filed litigation. Will courts be more willing to stay litigation for post-grant review?
  - Note: 325(b) where if an infringement action is filed three months after issuance, a court “may not stay its consideration of the patent owner’s motion for preliminary injunction” due to a post-grant review petition or proceeding.

# Post-grant Review: Estoppel

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- Estoppel in post-grant review is the same as *inter partes* review:
  - Triggered by the “final written decision” of the PTAB.
  - On a claim-by-claim basis.
  - Settlement available.
- But scope of post-grant review is broader than *inter partes* review, so estoppel as to “*any ground* that the petitioner raised or reasonably could have raised during that post-grant review” will likely have bite.
- Strategic consideration: what forum will provide the best opportunity to raise invalidity (not just based on patents or printed publications as in *inter partes* review)?

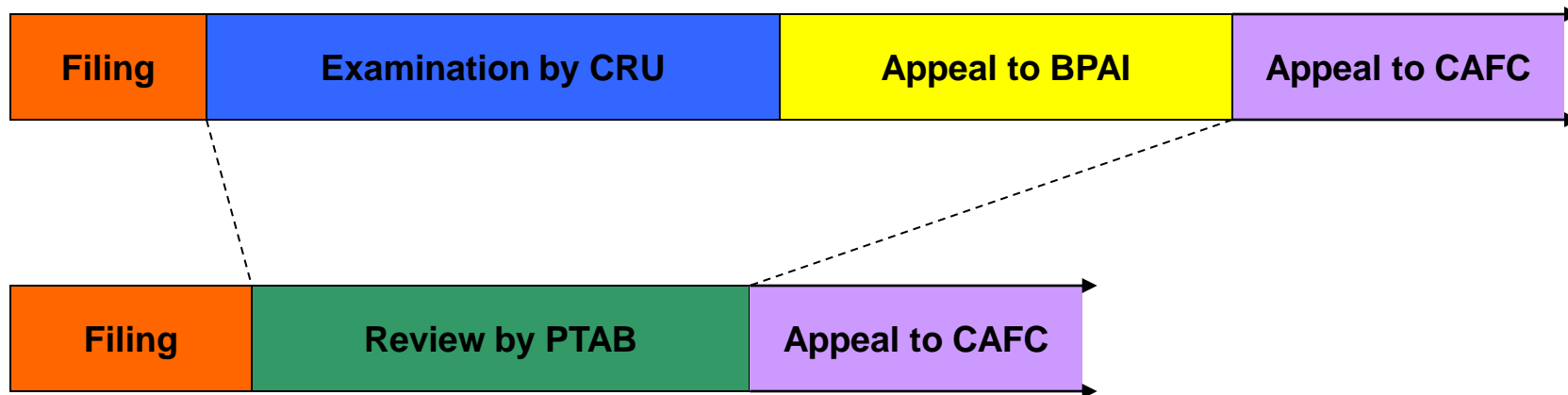
# *Inter Partes* Review: Petition

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- Scope: Only on the basis of prior art consisting of patents or printed publications.
- Patent Owner Input: Unlike *inter partes* reexamination, *inter partes* review allows a preliminary response by the patent owner *before* the Director determines whether to institute *inter partes* review.
- Threshold: Reasonable likelihood of prevailing.

# Inter Partes Review: Procedure

- Collapse of CRU examination and BPAI review into a single review conducted by Patent Trial and Appeal Board.
- AIA mandates final determination by PTAB within one year, with a six month extension.



# *Inter Partes* Review: Procedure

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- Burden on petitioner: preponderance of evidence.
- Discovery of relevant evidence, “including that such discovery shall be limited to (A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice.”
- Motions: to amend claims; to seal
- Comments by petitioner.
- Oral Hearing: either party.
- Multiple PTO Proceedings: joinder of multiple *inter partes* reviews; stay, transfer, consolidation with other co-proceedings

# *Inter Partes* Review: Estoppel

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- Estoppel is triggered by the “final written decision” of the PTAB.

VS.

- *Inter partes* reexamination, where estoppel is triggered by “any claim finally determined to be valid,” *i.e.*, completion of all appeals.
- One-year Statutory Deadline + Estoppel Trigger to PTAB decision = estoppel will be felt sooner in *inter partes* review than *inter partes* reexamination.
  - Will be felt in a civil action and ITC.

# *Inter Partes* Review: Estoppel

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- Overall estoppel-related considerations for *inter partes* review:
  - PTAB (no more CRU and BPAI)
  - One-year statutory deadline
  - Appeal to CAFC
  - Estoppel tied to PTAB decision, not CAFC decision
  - Estoppel: “reasonably” could have been raised
- Strategic consideration: what forum will provide the best opportunity to raise invalidity based on patents or printed publications?
- Can be settled without estoppel kicking in.

# Facts pointing to Reexam or Review

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- Highly complex technology
- Stay or avoid litigation
- Pay now vs. pay later

# *Ex Parte or Inter Partes?*

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- Ex parte is clearly cheaper and without estoppel, but potentially less rewarding
- Inter partes is clearly more expensive with estoppel, but with potentially greater reward
- Inter partes reexam vs. Inter partes review – a shift

# Summary Points

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Full effect of first-to-file deferred to new applications filed on or after 16 March 2013.

(of course earlier filed applications automatically win with few exceptions – e.g., new application inventor published before earlier filer, but within 1 year – could still swear behind?)

Interference proceedings replaced by derivation proceedings – still has to be filed within 1 year of patent issuance or publication of offending claim. Applies to applications/patents with claims having an effective filing date 16 March 2013 or later – otherwise interference proceedings are appropriate.

# Summary

Proceeding	Use	Availability	Threshold	Initial Decision Maker	Estoppel
Ex parte reexam	Anyone to challenge/address validity based on prior art	Now	SNQ	Examiners in CRU	None
Inter partes reexam	Third party to challenge validity based on prior art only patents on apps filed before 11/29/99	Now - 9/16/2012	A reasonable likelihood to prevail	Examiners in CRU	Any ground raised or could have raised
Inter partes review	Third party to challenge validity based on prior art	9/16/2012	A reasonable likelihood to prevail	Board	Any ground raised or reasonably could have raised
Post-grant review	Third party to challenge validity based on broad grounds	Patents effectively filed after 3/15/2013	More likely than not that the claim(s) is unpatentable	Board	Any ground raised or reasonably could have raised
Supplemental exam	Patent owner to address inequitable conduct issue proactively	9/16/2012	SNQ	Examiners in CRU	N/A

Did not discuss business methods patents.

# False Marking

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- Before the AIA:
  - Under 35 U.S.C. 292(b), any individual could bring a *qui tam* (“whistleblower”) action for false marking and could receive half the statutory penalties
  - Substantial statutory fines of \$500 “per offense” (as of 2009, interpreted as “per item”)
- After the AIA:
  - Only U.S. can sue for statutory penalties
  - Private right of action for compensatory damages only available to someone who has suffered “competitive injury” due to false marking
  - False Marking transformed from *qui tam* action to ordinary civil action for damages
  - No claims based on expired patents

# False Marking

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- *Retroactive effect* – applies to any case pending on or commenced after AIA signing date
  - Numerous cases have already been dismissed, some *sua sponte*
  - Potential 5<sup>th</sup> Amendment (takings clause) challenge to the AIA
  - However, the Supreme Court has upheld retroactive tax laws
- Future false marking claims likely to be much more rare due to difficulty of proving “competitive injury” (true competitors only)
  - End of the “False-marking trolls”
  - Pro-Business (manufacturers/retailers) reform

# Prior Use Defense

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Applicable if infringes a claim of a patent issued on or after 16 September 2011. So no old patents.

Commercial use in the U.S. at least 1 year before effective filing date or publication (whichever is earlier)

Regulatory Review counts.

Research at non-profit counts

## Limitations

- Personal – can't be transferred except as entire business

- Transferee can't change site of practice

- Only applies narrowly – not a general license

- Can't have abandoned the use

- Doesn't apply to "academic" patents.

# Questions

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