

America Invents Act

ACI's 13th Annual Maximizing Pharmaceuticals Patent Life Cycles Conference



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October 11, 2012



Patents Related Final Rules

Effective Date: September 16, 2012

- **Inventor's Oath or Declaration**
 - Applicability: Applications filed on or after September 16, 2012
- **Preissuance Submission**
 - Applicability: Pending or abandoned application filed before, on, or after September 16, 2012
- **Citation of Patent Owner Claim Scope Statement**
 - Applicability: Any patent on or after September 16, 2012
- **Supplemental Examination**
 - Applicability: Patent enforceable on or after September 16, 2012



Inventor's Oath/Declaration: Goals

- Statutory provision and final rules aim to:
 - streamline patent application filing;
 - simplify the content requirements for an oath/declaration; and
 - offer flexibility on the timing for filing an oath/declaration



Oath/Declaration and Application Data Sheet

- Inventor may be named by:
 - signed application data sheet (ADS) filed before or with an executed inventor's oath/declaration; or
 - executed inventor's oath/declaration
- Use of an ADS permits each oath/declaration to identify only the inventor executing the oath/declaration and not the entire inventive entity



Timing of Submission

- Oath/declaration may be postponed until the application is otherwise in condition for allowance provided that a signed ADS has been submitted:
 - identifying each inventor by his or her legal name; and
 - with a mailing address and residence for each inventor
- Oath/declaration must still be provided for a reissue application prior to examination
- Current surcharge is still required when the oath/declaration is not present on filing



Preissuance Submissions: Goals

- Statutory provision aims to improve the quality of examination and issued patents
- Final rule is designed to promote:
 - efficient processing of submissions; and
 - focused submissions of the most relevant documents



Preissuance Submissions

- Any third party may submit printed publications of potential relevance to the examination of an application for consideration and inclusion in the record of the application, per 35 U.S.C. 122(e)
 - Submissions will be considered by Examiner in the same manner as documents cited on an IDS
 - Must be made before the later of:
 - 6 months after the date on which the application is first published by the Office; or
 - date of first rejection of any claim by the examiner
- AND**
- before the date a notice of allowance is given or mailed



Citation of Patent Owner Claim Scope Statements: Goals

- Statutory provision aims to prevent the patent owner from presenting different positions on claim scope for the same claims in the same patent in different proceedings
- Final rule designed to:
 - facilitate the filing and review of these statements;
 - prevent improper consideration of submissions; and
 - preserve the integrity of patent files



Citation of Patent Owner Claim Scope Statements

- 35 U.S.C. 301 expands the scope of information that may be submitted in a patent beyond prior art to include written statements about the scope of the patent claims filed by the patent owner in a federal court or USPTO proceeding
- Governs Office Usage
 - USPTO will not use a patent owner claim scope statement in deciding whether to order an *ex parte* or *inter partes* reexamination or institute an administrative trial
 - After ordering, USPTO may take a patent owner claim scope statement into account to determine the proper meaning of the patent claims



Supplemental Examination: Goals

- Statutory provision aims to provide patentees with a mechanism to immunize a patent from allegations of inequitable conduct
- Final rules designed to:
 - create a process that allows for completion of the supplemental examination within the 3-month statutory time frame and for prompt resolution of any ex parte reexamination; and
 - avoid a post-patent process involving large submissions of unexplained documents (like IDS practice)



Supplemental Examination: Request

- Request for supplemental examination may be filed only by the patent owner
- Request may be filed at any time during the period of enforceability of the patent, e.g., generally 6 years after expiration of the patent
- Third party may not request supplemental examination or participate in a supplemental examination



Supplemental Examination: Contents of Request

- Identification of the patent and of each claim for which supplemental examination is requested;
- List of the items of information requested to be considered, reconsidered, or corrected;
- Separate, detailed explanation of the relevance and manner of applying each item of information to each identified patent claim;
- Summary of the relevant portions of any submitted document, other than the request, that is over fifty pages in length; and
- Fees

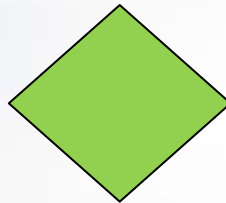


Supplemental Examination: Request Processing

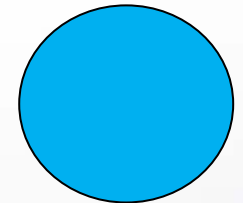
Patent Owner
Request



Decision on Patent Owner
Request: substantial new
question of patentability
(SNQ) Standard Triggered?



Supplemental Examination
Concluded and *Ex Parte*
Reexamination Initiated



Supplemental
Examination
Concluded -
Electronic Issuance of
certificate



Reexamination Practice

- *Inter Partes* reexamination is modified by AIA and is phasing out
- *Inter Partes* Review will replace *Inter Partes* reexamination, but overlap will occur
- Extraordinary numbers of both *Inter Partes* Reexamination filings and *Ex Parte* Reexamination filings were received in September 2012
 - Filings in first three weeks of September represented over half of all last year's filings (300 EP, 350 IP)
 - *Inter partes* reexamination filings through September 21 were equivalent to 96% of all IP filings last year



Administrative Patent Trials

Effective Date: September 16, 2012

- *Inter Partes* Review
- Post-Grant Review
- Covered Business Methods Review
- Derivation Proceedings



Considerations in Formulating Final Rules

- AIA provides that the Office consider:
 - effect of the regulations on the economy;
 - integrity of the patent system;
 - efficient operation of the Office; and
 - ability to timely complete the proceedings
- Legislative history provides that proceedings reflect a quick, effective, and efficient alternative to often costly and protracted district court litigation



Trial Rules

Inter Partes Review
§§ 42.100 – 42.123

Post-Grant Review
§§ 42.200 – 42.224

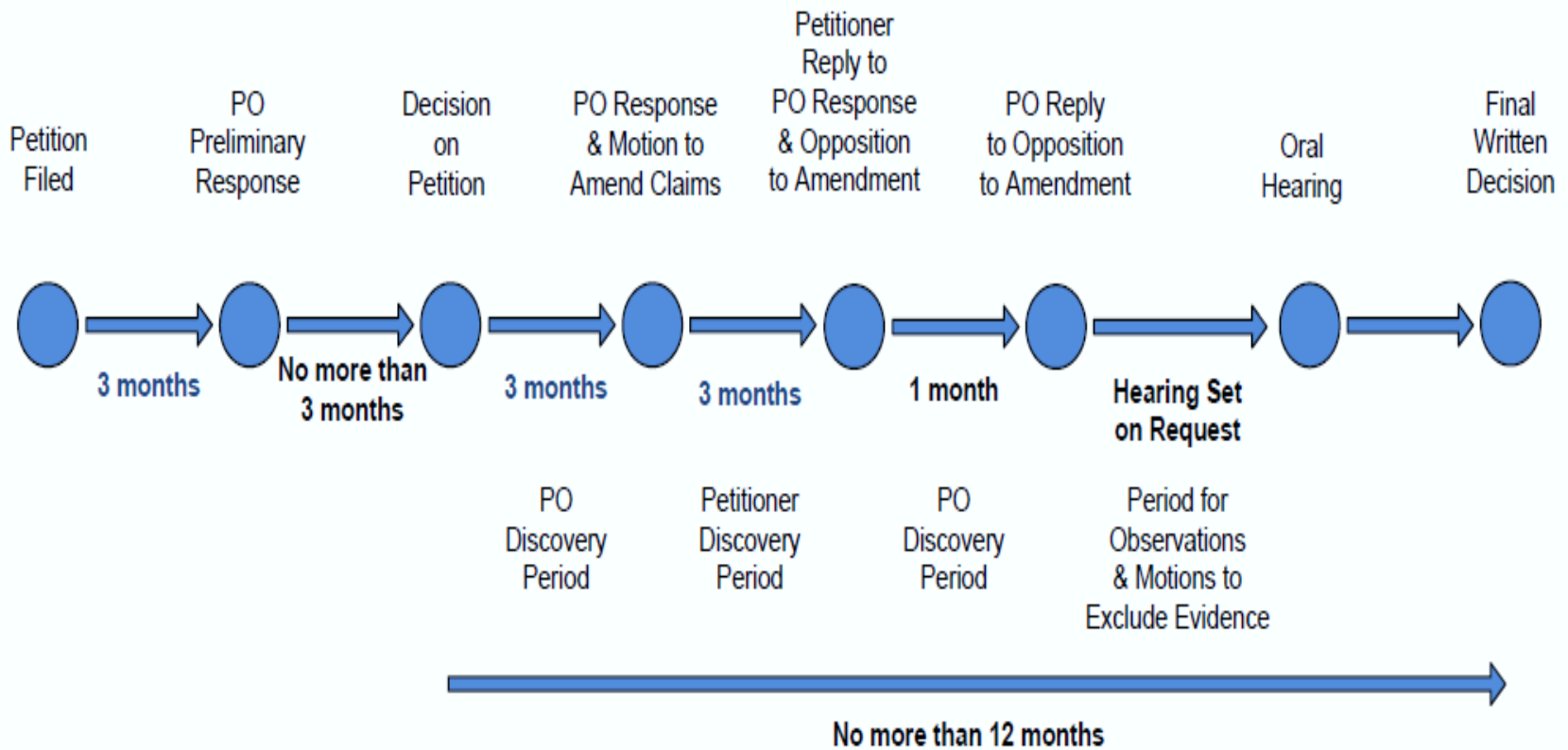
Umbrella Trial Rules
§§ 42.1 – 42.80

Covered Business
Method Patent Review
§§ 42.300 – 42.304

Derivation Proceeding
Proposed §§ 42.400 –
42.412



Trial Proceedings



PO = Patent Owner



Major Differences between IPR, PGR, and CBM

IPR

All patents are eligible

Petitioner has not filed an invalidity action and petition is filed no more than one year after service of infringement complaint for the patent

Only §§ 102 and 103 grounds based on patents or printed publication

PGR

Only FITF patents are eligible

Petitioner has not filed an invalidity action

Only §§ 101, 102, 103, and 112, except best mode

CBM

Both FTI & FITF patents are eligible, but must be a covered business method patent

Petitioner must be sued or charged w/ infringement

Only §§ 101, 102, 103, and 112, except best mode

FTI = First to Invent

FITF = First Inventor to File



Threshold Standards for Institution

IPR

Petition must demonstrate a **reasonable likelihood** that petitioner would prevail as to at least one of the claims challenged

PGR/CBM

Petition must demonstrate that it is **more likely than not** that at least one of the claims challenged is unpatentable

PGR/CBM: Greater than 50% chance

IPR: May encompass a 50/50 chance



Time Windows to File IPR/PGR/CMB Petition

First-to-Invent
Patents

CBM
After issuance

IPR
> 9 months
from issue date

First-Inventor-
to-File
Patents

PGR
 \leq 9 months
from issue date

IPR or CBM
> 9 months
from issue date



Inter Partes Review: Features

- All patents are eligible
- Third party who has not previously filed a civil action challenging the validity of a claim
- Request to cancel as unpatentable based only on patents or printed publications under § 102 or § 103
- Filed after the later of:
 - 9 months after the grant of a patent or issuance of a reissue of a patent; or
 - date of termination of any post grant review of the patent

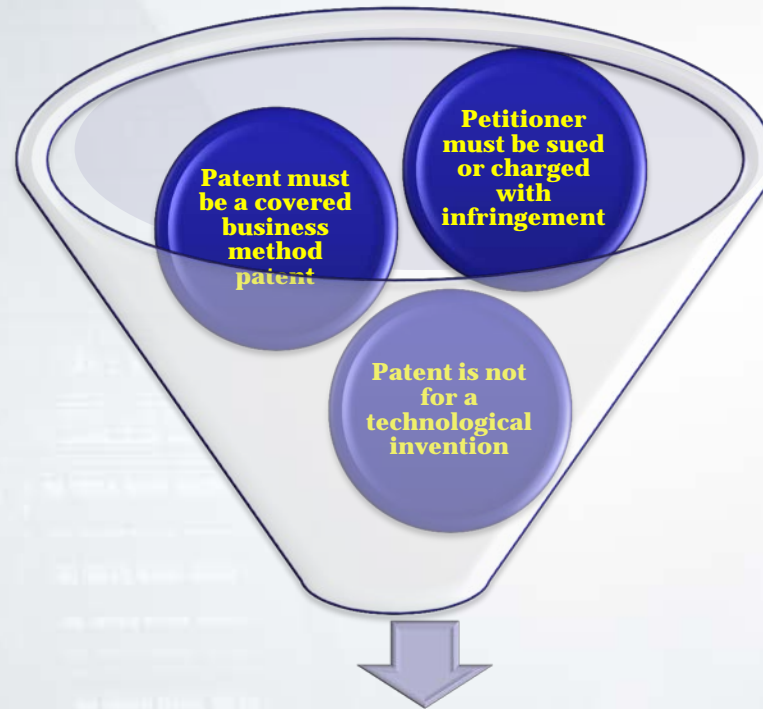


Post-Grant Review

- Most aspects of PGR and IPR are effectively the same
- Some differences as compared with IPR:
 - With limited exceptions, only those patents issuing from applications subject to first-inventor-to-file provisions are eligible
 - Challenges may be based on §§ 101, 102, 103, and 112, except best mode
 - Only be requested on or prior to the date that is 9 months after the grant of a patent or issuance of a reissue patent
 - Petition must demonstrate that it is more likely than not (*i.e.*, a higher threshold than IPR) that at least one of the claims challenged in the petition is unpatentable



Covered Business Methods



CBM Review



Derivation

- Only a patent applicant may file
- Must be filed within 1 year of the date of the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention

“The first publication” means either a patent or an application publication under 35 U.S.C. 122(b), including a publication of an international application designating the U.S. as provided by 35 U.S.C. 374

- Must have a claim that is the same or substantially the same as a respondent's claim, and the same or substantially the same as the invention disclosed to the respondent

“Same or substantially the same” means patentably indistinct



Derivation

- Must set forth basis for finding that an inventor named in an earlier application or patent derived the claimed invention
- **Must certify that the inventor from whom the invention was derived did not authorize the filing of the earliest application claiming such invention**
- Must provide substantial evidence, including one affidavit, in support of the petition to show how the invention was communicated to the respondent
- Not likely to be instituted, even if standard is met, until a patent with the claimed invention issues



Patent Review Processing System (PRPS) Filing System

- PRPS Telephone Help Line: 571-272-PTAB
- E-mail: Trials@USPTO.gov
- Website: <http://www.uspto.gov/ptab>



First Inventor to File

- Effective Date: March 16, 2013
- Comments Due: November 5, 2012 (reopened)



First Inventor to File: Goals

- Provide guidance to examiners and the public on changes to examination practice in light of the AIA
- Address examination issues raised by the AIA
- Provide the Office with information to readily determine whether the application is subject to the AIA's changes to 35 U.S.C. 102 and 103



First Inventor to File

- Transitions the U.S. to a first-inventor-to-file patent system while maintaining a 1-year grace period for inventor disclosures
- Prior public use or prior sale anywhere qualifies as prior art (prior public use and sale is no longer limited to the U.S.)
- U.S. patents and patent application publications are effective as prior art as of their priority date (no longer limited to U.S. priority date), provided that the subject matter relied upon is disclosed in the priority application
- Applies to:
 - Claim with an effective filing date on or after March 16, 2013; and
 - Claim for benefit to an application that ever had a claim with an effective filing date on or after March 16, 2013



Framework

Prior Art	Exceptions	Label
102(a)(1)	102(b)(1)(A)	Grace Period Inventor Disclosures & Grace Period Non-inventor Disclosures
	102(b)(1)(B)	Grace Period Intervening Disclosures
102(a)(2)	102(b)(2)(A)	Non-inventor Disclosures
	102(b)(2)(B)	Intervening Disclosures
	102(b)(2)(C)	Commonly Owned Disclosures



Fee Setting: Proposed Rule

- Fee Setting
 - Patent Fees Proposed Rule (77 Fed. Reg. 55028, September 6, 2012)
- Comments due: November 5, 2012



Fee Setting: Goals and Strategies

- Ensure the patent fee schedule generates sufficient aggregate revenue to recover the aggregate cost to achieve two significant USPTO Goals:
 - Optimize patent timeliness and quality; and
 - Implement a sustainable funding model for operations
- Set individual fees to further key policy considerations:
 - Fostering innovation;
 - Facilitating the effective administration of the patent system; and
 - Offering patent prosecution options to applicants
- Comments are due November 5, 2012.



AIA Help

- AIA Telephone Help Line: 1-855-HELP-AIA
- E-mail: HELPAIA@uspto.gov
- USPTO Microsite (consistently updated):
http://www.uspto.gov/aia_implementation/index.jsp
- Website for the full 166 page AIA slide set:
http://www.uspto.gov/aia_implementation/120910-aia-roadshow-slides.pdf



Appendix

- Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act: Final Rule, 77 Fed. Reg. 48776 (August, 14, 2012)
- Changes to Implement Supplemental Examination Provisions of the Leahy-Smith America Invents Act: Final Rule, 77 Fed. Reg. 48828 (August 14, 2012)
- Changes to Implement the Preissuance Submissions by Third Party Provisions of the Leahy-Smith America Invents Act: Final Rule, 77 Fed. Reg. 42150 (July 17, 2012)
- Changes to Implement Miscellaneous Post Patent Provisions of the Leahy-Smith America Invents Act: Final Rule, 77 Fed. Reg. 46615 (August 6, 2012)



Appendix

- Changes to Implement the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 43742 (July 26, 2012)
- Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act , 77 Fed. Reg. 43759 (July 26, 2012)

Thank You

