

Navigating the New Provisions and Procedures of the America Invents Act



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CBI's 4th Life Sciences Congress on Paragraph IV Disputes



The Leahy-Smith America Invents Act, P.L. 112-29

- Most significant change in patent law since 1836
- Provisions discussed over the course of five Congresses while:
 - Active discussion in the courts and in industry on what needs to be addressed in real patent reform
 - Significant backlog at the agency and significant efforts to address it



America Invents Act

Goals of Patent Reform Legislation

- Encourage innovation and job creation
- Support USPTO's efforts to improve patent quality and reduce backlog
- Establish secure funding mechanism
- Provide greater certainty for patent rights
- Provide less costly, time-limited administrative alternatives to litigation



Enactment Timeline

Day of Signing Sep 16, 2011	10 Days Sep 26, 2011	Oct 1, 2011	60 days Nov 15, 2011	12 Months Sept 16, 2012	18 Months Mar 16, 2012
<p>Reexamination transition for threshold</p> <p>Tax strategies are deemed within prior art</p> <p>Best mode</p> <p>Human organism prohibition</p> <p>Virtual and false marking</p> <p>Venue change from DDC to EDVA for suits brought under 35 U.S.C. §§ 32, 145, 146, 154 (b)(4)(A), and 293</p> <p>OED Statute of Limitations</p> <p><u>Fee Setting Authority</u></p> <p>Establishment of micro-entity</p> <p>11/29/2012</p>	<p><u>Prioritized examination</u></p> <p>15% transition surcharge</p>	<p>Reserve Fund</p>	<p>Electronic filing incentive</p>	<p>Inventor's oath/declaration</p> <p><u>Third party submission of prior art for patent application</u></p> <p><u>Supplemental examination</u></p> <p>Citation of prior art in a patent file</p> <p>Priority examination for important technologies</p> <p><u>Inter partes review</u></p> <p><u>Post-grant review</u></p> <p><u>Transitional post-grant review program for covered business method patents</u></p>	<p><u>First-to-File</u></p> <p>Derivation proceedings</p> <p>Repeal of Statutory Invention Registration</p>



Prioritized Examination

Effective September 26, 2011

- Expedited Review of a patent application with the goal of final disposition (e.g., mailing notice of allowance, mailing final office action) within twelve months from the date of the grant of prioritized status
- Original, non-provisional utility or plant patent application accorded special status for expedited examination if:
 - \$4,800 fee, reduced by 50% for small entity;
 - no more than 4 independent claims, 30 total claims, and no multiple dependent claims; and
 - Utility applications must be filed electronically (EFS-Web); Plant applications must be filed via paper.



Prioritized Examination

- Prioritized examination (Track I) is available for Requests for Continued Examination
 - Effective December 19, 2011
 - Only a single track I request associated with an RCE under 37 CFR 1.114 may be granted in an application
- Track I may be requested for a continuing application
- Track I does not apply to international, design, reissue, or provisional applications or in reexamination proceedings



Prioritized Examination Statistics (as of 10/11/12)

Petitions Filed	Average Days to Petition Decision	% Petitions Granted	Average Days from Petition Grant to First Office Action
6019	36.8	95%	50

First Action on Merits mailed	Final Actions mailed	Allowances Mailed	Average Days from Petition Grant to Allowance	Average Days from Petition Grant to Final Disposition
3,929	1017	1085	129	158



Preissuance Submissions

Effective Date: September 16, 2012

- Applicability: Pending or abandoned application filed before, on, or after September 16, 2012
- 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)
- Must be timely made in writing and include:
 - Concise description of asserted relevance of each document;
 - Fee;
 - Statement of compliance with statute;
 - Document List
 - Copies of documents (not U.S. patents and U.S. Pre-Grant publications)
 - Translations for any non-English language documents



Preissuance Submissions: Statutory Time Periods

- 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
-
- Submissions (documents and concise descriptions) made during this time period will be considered by Examiner in the same manner as documents cited on an IDS



Supplemental Examination:

Effective Date: September 16, 2012

- Applicability: Patent enforceable on or after September 16, 2012
- 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



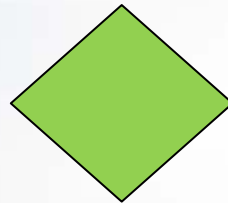
Supplemental Examination: Request Processing

Patent Owner
Request



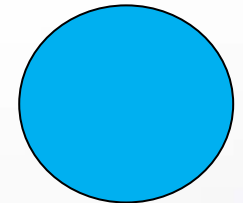
3 months

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



YES

Supplemental Examination
Concluded and *Ex Parte*
Reexamination Initiated



NO

Supplemental
Examination
Concluded -
Electronic Issuance of
certificate



Paragraph IV Disputes & Supplemental Examination

- Supplemental Examination
 - Permits a patent owner to request that the Office consider, reconsider, or correct information believed to be relevant to the patent
 - These provisions could assist the patent owner in addressing certain challenges to the enforceability of the patent during litigation
 - Cannot request supplemental examination if the provisions shall not apply when an allegation has been pled with particularity in a notice under 505(j)(2)(B)(iv)(II) of the FDCA before the filing of a request for supplemental examination



Administrative Patent Trials

Effective Date: September 16, 2012

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



Trial Rules

Inter Partes Review
§§ 42.100 – 42.123

Post-Grant Review
§§ 42.200 – 42.224

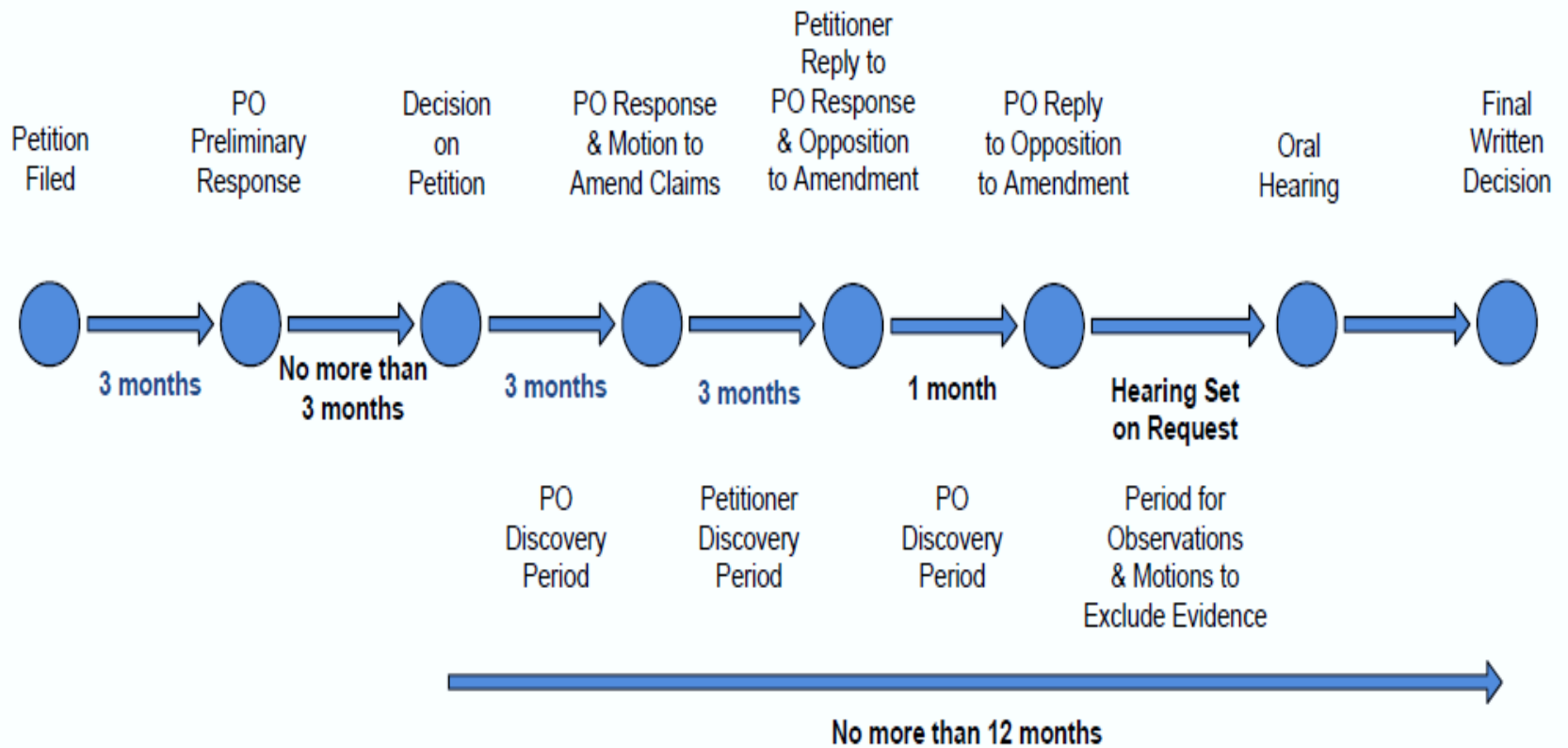
Umbrella Trial Rules
§§ 42.1 – 42.80

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/CBM 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 Reexamination and *Inter Partes* Review

- *Inter partes* reexamination was modified and eventually phased on 09/16/12 out by AIA
- *Inter Partes* Review replaces *inter partes* reexamination, but there will be overlap
- Increased filings of *Inter Partes* Reexamination filings and *Ex Parte* Reexamination Filings were received in September 2012 (> 650)



Inter Partes Review

- 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

- Employ the PGR standards and procedures subject to certain exceptions
- Some differences with PGR:
 - Cannot file CBM petition during time a PGR petition could be filed, *i.e.*, 9 months after issuance of a patent
 - Petitioner must be **sued or charged with infringement**
 - Petitioner has burden of establishing that patent is eligible for CBM review
 - Prior art is limited when challenging a first-to-invent patent

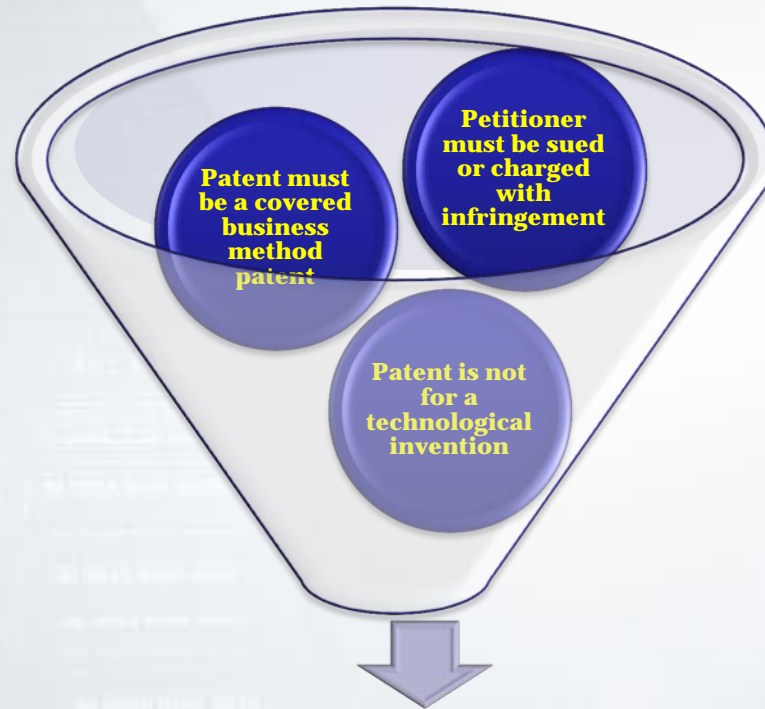


Covered Business Methods: Eligible Patents

- Both first-to-invent and first-inventor-to-file patents are eligible
- Must be a covered business method patent
 - Generally defined in the AIA as a method or corresponding apparatus for performing data processing or other operations for financial product or service
 - Definition excludes patents for technological inventions
- Based on what the patent claims, *i.e.*, a patent having one or more claims directed to a covered business method is eligible for review



Covered Business Methods



CBM Review



Paragraph IV Disputes & Post Issuance Patent Opposition

- Post-Issuance patent opposition procedures before USPTO:
 - What's available? Supplemental examination, ex parte reexamination, inter partes review, and post-grant review.
 - Conclusion of any proceeding could invalidate patent, but no 30-month stay for brand and no 180-day exclusivity for ANDA filer.
- Patent litigation before Federal District pursuant to 35 USC 271(e)(2):
 - Conclusion of litigation could invalidate patent, 30 month-stay to brand and 180-day exclusivity to ANDA filer.



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 Proposed Rule

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

