The Comprehensive Guide to

Patent Reform

The critical industry forum on The Leahy-Smith America Invents Act

January 23-24, 2013 • Doubletree Suites Times Square Hotel • New York, NY

Experts from the USPTO:

Keynote Speaker

Teresa Stanek Rea
Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO
United States Patent and Trademark Office (Alexandria, VA)

Thomas Giannetti
Patent Administrative Judge
United States Patent and Trademark Office (Alexandria, VA)

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Molecular Templates
Novo Nordisk
Sanofi Pasteur

Top patent counsel from international corporations, leading prosecution and litigation experts in private practice, and senior PTO officials will share in-depth analysis and practical guidance on the generation-defining changes to Title 35 U.S.C. encompassed in the America Invents Act. Attend to participate in advanced discussions on:

- ADAPTING to the first-to file regime and DEVELOPING prosecution techniques to ensure timely filings that result in robust patents
- DISSECTING the new rules covering the usage of declarations and assignments to avoid costly delays and confusion associated with recalcitrant or missing inventors
- UTILIZING the *inter partes* review process to challenge troubling patents and UNDERSTANDING the discovery rules associated with this procedure
- DETERMINING when it is appropriate to employ the post-grant review procedure to attack a rival patent and CRAFTING defenses to it
- GRASPING the advantages of supplemental examination, its potential to cure defects in prosecution, and RECOGNIZING its risks
- MAXIMIZING the potential of third party prior art submission in attacking a rival patent pre-issuance and GUARDING against its effects with smart prosecution
- UNDERSTANDING the implications of patent reform for Hatch-Waxman litigation
- DEMYSTIFYING the new standards for prior art encoded in the America Invents Act including discussion of the new "disclosures" definition, the impact on obviousness findings, and more

Gain Added Learning Value by Attending the Pre- and Post-Conference Workshops:

January 23, 2013
A: Patent Reform 101: A Primer on the Fundamental Provisions of the America Invents Act

January 25, 2013
B: Interactive Working Group Session: A Hypothetical Invention Being Patented Under the AIA

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Caesar:

Who is it in the press that calls on me?

I hear a tongue shriller than all the music

Cry "Caesar!" Speak, Caesar is turn'd to hear.

Soothsayer:

Beware The Ides of March.

- *Julius Caesar*, Act 1, scene 2

March 15, 2013 is the last day for the decades-old U.S. patent regime, and for patent attorneys, this date is every bit as foreboding for them as it was for Caesar himself. The America Invents Act (AIA) is ushering in a raft of new rules and spawning regulations that upend generations of established prosecution and litigation practices, leaving no small amount of fear and consternation in its wake. But the Act also presents savvy practitioners with opportunities to enhance their IP portfolios' value and undermine rivals' patents - thanks to a bevy of new pre-and post-issuance procedures.

Nevertheless, the full effects of countless nuances sprinkled throughout the AIA and the full implications of regulations promulgated under it remain unknown, and patent practitioners are left with a multitude of questions regarding the potential ramifications for their craft. With so much at stake, you must develop a plan to address both the changes already in effect and those whose coming implementation looms just one day past that fateful date - the *Ides of March*.

American Conference Institute's **2nd Comprehensive Guide to Patent Reform** once again unites experienced in-house counsel from top innovators, private practice experts, and senior officials from the USPTO to answer patent professionals' most pressing questions, including:

- What does "first to file" actually mean under the AIA requirements? Which system can you or should you file under – the current first to invent or the new first to file (or both)? And how do you avoid first-to-file bubble filings before 3/15/2013?
- When can on-sale and public use activity be considered prior art? Has secret §102(f) prior art been eliminated?
- Do you need to include best mode in the application or not and what happens if you don't? Is best mode completely toothless now? How will examiners be able to address the best mode issue?
- What will be required in the PGR process? What type of discovery? Expert witnesses? How do the estoppel provisions alter your analysis of whether to engage in the PGR system?
- What estoppel provisions are associated with IPRs and how are these different from the inter partes reexamination provisions? When do you file a 3rd party parallel IPR?

Do not miss this opportunity to join your colleagues in an advanced think-tank discussion regarding the practical impact of patent reform on innovation and patent practice. As this event is sure to sell out, reserve your place today to ensure you are a part of the discussion and have the information that you need to navigate this radically different legal landscape by calling **888-224-2480**, faxing your registration form to **877-927-1563** or registering on-line at **www.americanconference.com/patentreform**.

ETHICS

Workshop A: Wednesday, January 23, 2013

9:00 – 12:00 (Registration and Continental Breakfast at 8:15)

Patent Reform 101: A Primer on the Fundamental Provisions of the America Invents Act

Ryan L. Marshall
Intellectual Property Attorney
Brinks, Hofer, Gilson, & Lione, P.C. (Salt Lake City, UT)

James J. Mullen, Ph.D.
Partner
Morrison & Foerster, L.L.P. (San Diego, CA)

The America Invents Act (AIA) wrought vast changes on what it is arguably the most complex and heavily litigated part of the United States Code this side of Title 26. These changes not only fundamentally alter inventorship, patentability, prior art, and best mode, but they also create entirely new procedures for challenging patents outside federal court. In addition, myriad smaller changes to the code lay waiting to trip up even the most diligent prosecutors and litigators. As a result, it is vital to be certain that you are aware of the major changes to Title 35 U.S.C., and this pre-conference primer's faculty of in-house and private practice experts will provide you with a clear overview of the numerous sections of the Act that will be the subjects of intensive strategic analysis in the general session. Topics to be discussed will include:

- Definitions in the Act explained
- Outlining the provisions impacting prosecution
  - o First-to-file inventorship
  - o Accelerated examination
  - o Prior art and preissuance
  - o Public "disclosure" defined
  - o Derivation proceedings
  - o Best mode inclusion
- An overview of the litigation and procedural provisions
  - o Inter partes review
  - o Post grant review
  - o 3rd party prior art submission
  - o Supplemental examination and reexamination
  - o Venue, jurisdiction, and procedural matters
  - o False marking changes
- Financial provisions laid out in the AIA
  - o Fees and fee setting authority
  - o Tax consequences
  - o Funding and expenses
- The AIA's impact on universities and academic institutions
  - o How the first-to-file system will affect academic innovation
  - o How the AIA advantages universities
- Prioritized examination
  - o Determining which technologies can qualify as "important technologies"
  - o Data and information required to be eligible for a prioritized examination
- Changes to Patent Term Extension calculations
- Changes to declarations and assignments
- Studies and satellite offices
- Micro-entity certification provisions
  - o Qualifying as a micro-entity
  - o The risks associated with obtaining micro-entity status
  - o Fee reduction provisions
- Identifying what was not included in the AIA and the current status of these initiatives
  - o The current status of inequitable conduct under new guidance set forth in Therasense and the impact of changes to supplemental examinations in the AIA on inequitable conduct
  - o Applicant Quality Submissions
  - o Stays of post-issuance proceedings
  - o Limits on injunctions
  - o Interlocutory appeals of claim construction

General Session Day 1

12:00 **Registration**

1:00 **Co-Chairs' Opening Remarks**

Michelle Lewis
Vice President of Intellectual Property
Molecular Templates (Newark, NJ)

Mercedes Meyer, Ph.D.
Partner
Drinker, Biddle, & Reath, L.L.P. (Washington, DC)

1:15 **USPTO Keynote Address: The USPTO's Efforts to Implement AIA Provisions Impacting Patent Prosecution**

Teresa Stanek Rea
Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO
United States Patent and Trademark Office (Alexandria, VA)

In this exclusive keynote address detailing the AIA's effects on patent prosecution, Deputy Rea will outline the PTO's thought process in developing the regulations covering the first-to-file system, the changes to declaration and assignment provisions of 35 U.S.C. § 118, public disclosures and prior art, and the new best mode standard. In addition, Deputy Rea will discuss the protocols to be applied to help examiners navigate what are effectively two sets of rules for the foreseeable future. Other topics to be discussed will include how AIA implementation has worked so far and Deputy Rea's thoughts on how provisions to be implemented March 16, 2013 date will impact the PTO.

2:00 **Preparing Your Company for the Looming Implementation of the First-to-File Regime and Preparing Strategies to Exploit the Coming Changes for Maximum Benefit**

Nicholas Boivin
Director Intellectual Property Counsel
Cubist Pharmaceuticals (Lexington, MA)

Eric J. Sosenko
Shareholder
Brinks, Hofer, Gilson, & Lione, P.C. (Ann Arbor, MI)

Harold C. (Hal) Wegner
Partner
Foley & Lardner, L.L.P. (Washington, DC)

- Timing your filing – which rules do you want?
  - o Explaining the difference between the pre- and post-March 16, 2013 filing date
  - o Ensuring that every claim is supported by a pre-AIA priority filing
  - o What is sufficient to support a pre-AIA filing?
  - o Why is it important to amend prior to March 16, 2013?
- Filing strategies in light of the March 16, 2013, change:
  - o Focusing on the statutory requirements (enabled embodiment for § 112(a) support), claims of varying scope
  - o Rolling provisionals to supplement exemplary support and provide additional subgeneric definitions
  - o Avoiding prior art mention or characterization in a Background of the Invention (while identifying prior art in an Information Disclosure Statement)
  - o Avoiding "objects", "gist" and other MPEP-mandated elements. Grasping the changes to the grace period under the AIA
  - o Eliminating the ability to swear behind
- Including layers of protection into an application
  - o Specifying particular embodiments
  - o Elaborating on alternative embodiments to establish enablement for broader claims
- Determining why documentation of invention date is still important
  - o Establishing prior user rights
  - o Rebutting a derivation proceeding
  - o Initiating a derivation proceeding
- Barring a third party application with strategic publication
  - o Recognizing loss of foreign rights
  - o Outlining usefulness in a university setting
  - o Eliminating a third party's ability to file for species not included in your publication
- Maintaining a heightened vigilance for third party publications
  - o Filing prior to March 16, 2013 when third party publications are found

  Preserving the ability to swear behind third party art
- Discussing the sufficiency and insufficiency of trade secret protection in lieu of patent filing
- Adapting to the shift towards derivation practice
  - o Defining differences between derivation and previous opposition proceedings
  - o What are the limitations and benefits of derivation proceedings
  - o Proving or disproving that a disclosure was actually derived from the inventor
  - o Why is maintenance of meticulous notebook-keeping still important?

3:15 **Afternoon Refreshment Break**

3:30 **Identifying What Constitutes Prior Art Under the AIA and Planning a Patenting Strategy Around the New Standards**

John Todaro
Managing Counsel - Patents
Merck (Rahway, NJ)

Michele A. Cimbala, Ph.D.
Director
Sterne, Kessler, Goldstein & Fox P.L.L.C.
(Washington, DC)

Adda Gogoris
Partner
Merchant & Gould, P.C. (Washington, DC)

- Coping with the increased amount of public information that can be used against an applicant
- Preparing for the shift to include prior art based on the "effective filing date" and not the date of invention
  - o Eliminating the ability to swear back
  - o Nonobvious subject matter under revisions to § 103
- Applying "disclosure" exceptions to the new prior art requirements
  - o How is "disclosure" defined under the regulations?
  - o Understanding what will constitute disallowed "disclosures" and avoiding inadvertent mistakes
- When can on-sale and public use activity be considered prior art?
  - o Has secret § 102(f) prior art been eliminated?
- Exploring changes to § 102(e) practice and the apparent elimination of the Hilmer Doctrine
- Appreciating the expanded prior user rights doctrine under the AIA
  - o Grasping the exception to this doctrine for universities
- Updating prior art searches to include third party prior art
- Obtaining guidance for conducting global prior art searches
  - o Comparing what constitutes prior art in the US vs. abroad and the potential risks of inadvertent creation of prior art impacting patent application approvals globally
  - o Determining the implications of changes to novelty and nonobviousness in the AIA in comparison to absolute novelty in Europe

4:30 **Slipping the Gordian Knot – How to Avoid Ethical Conundrums Presented by the AIA's Inconsistent Best Mode Requirements**

ETHICS

MaCharri Vorndran-Jones
Patent Counsel, Diabetes/Endocrinology
Eli Lilly & Co. (Indianapolis, IN)

Mercedes Meyer, Ph.D.
Partner
Drinker, Biddle, & Reath, L.L.P. (Washington, DC)

35 U.S.C. § 282 has been amended to disallow failure to include best mode as a basis for invalidating a patent; nevertheless, 35 U.S.C. § 112 still requires inclusion of best mode as a requirement to obtain a patent. Practitioners are left scratching their heads over this inconsistency and fearing charges of inequitable conduct in the face of likely pressure from clients to avoid giving away an invention's "special sauce" when drafting a patent application. During this panel, our faculty of experts will discuss how to deal with clients demanding that practitioners conceal key elements of best mode, how to respond to an examiner's demand for proof of best mode under 37 CFR 1.105, overcoming this inherent conflict of interests, and more.

5:30 **Conference Adjourns to Day 2**

8:45 **Co-Chair's Opening Remarks**

9:00 **USPTO Address: Detailing the New Post Grant Opposition Procedures, How They Will Impact Patenting, and More**

Thomas Giannetti
Patent Administrative Judge
United Stated Patent & Trademark Office (Alexandria, VA)

This exclusive address by Judge Giannetti will outline the regulations covering the brand new post grant review, inter partes review, supplemental examination, and third party pre-issuance submission procedures and how they will affect patent prosecution and litigation. Judge Giannetti will discuss the PTO's thought process in crafting these regulations, especially with regard to discovery rules and standards of evidence, and take questions from attendees on utilizing or defending against them.

9:45 **Learning the Sweet Science: Win the New Boxing Match Known as *Inter Partes* Review**

Kimberly Prior
Senior Counsel
Hoffman-LaRoche, Inc. (Nutley, NJ)

Allen R. Baum
Chair of the Chemical Practice Group
Brinks, Hofer, Gilson & Lione, P.C. (Morrisville, NC)

Scott McBride
Shareholder
McAndrews, Held, and Malloy, Ltd. (Chicago, IL)

- Identifying which patents are most susceptible to IPR
  - o Understanding how the proceedings are limited to prior art
- Examining how inter partes reexamination procedures are being employed by both patent challengers and patent holders in different scenarios
  - o Questions of economics, efficiencies, and risk
  - o What can we glean from these current behaviors relative to the future utilization of inter partes review?
- Preparing for potential IPR review of patents granted prior to November 1999
- How to bunt the IPR process for "crown jewel" patents
- When to file a third party parallel IPR
- What are the discovery rules for IPR?
  - o Utilizing the discovery rules to defend against an IPR proceeding
  - o How and when to use expert witnesses
- How do re-issuance proceedings and reexam impact IPR strategy?
- Understanding the fine points of the new inter partes review procedure
  - o Considerations for choosing this forum
  - o Timing, cost, speed of resolution
- Grasping revisions to patent challenger's burden of proof under inter partes review procedures
  - o Substantial new question of patentability vs. reasonable likelihood that the petitioner will prevail on claim
- Exploring the scope of review for current and new procedures under § 102 and § 103
  - o Patents (prior art) and publications
  - o Comprehending the relationship between scope of review and estoppel
- Transition and phase out
  - o Examining the interplay between the timing for post grant review and inter partes review
  - o Transition in presiding forums
- Choosing between the Central Reexam Unit (CRU) vs. Patent Trial and Appeal Board (PTAB)
  - o Appeaing to CAFC

11:00 **Morning Coffee Break**

11:15 **Preparing for the Eventual Employment of the Post Grant Review Procedure in Opposition Practice**

Stephen Perkins
Associate General Counsel IP
Covidien Surgical Solutions (Boulder, CO)

Steve Lendaris
Special Counsel
Baker Botts, L.L.P. (New York, NY)

- Weighing considerations for when a challenge should be brought under post grant review (PGR)
- Exploring start dates, timing and basis of the application – questions to ask
  - o Is the challenge brought within nine months of patent issuance?
  - o What is the basis of the invalidity challenge
- Estoppel considerations looking ahead to potential litigation
- Raising all bases for invalidity lest you be precluded from raising them in other PTO or district court proceedings
- Examining the mechanics, protocols and procedures for PGR
  - o Filing of petition
  - o Analogous nature of proceeding to district court litigation
  - o Discovery
  - o Hearings
  - o Motions
  - o Settlement
  - o appearing before the Patent Trial and Appeals Board (PTAB)
- Analyzing the petitioner's burden of proof
  - o Proving that it is "more likely than not that one of the claims challenged in the petition is unpatentable"
- Procedures for appeal

12:15 **Networking Lunch**

1:30 **Deciding When to Use Supplemental Examination to Cure Defects in a Patent: Balancing the Risks and Rewards**

Maggie Shafmaster, Ph.D.
Vice President, Chief Patent Counsel
Sanofi Pasteur (Cambridge, MA)

Frank W. Forman
Senior Patent Counsel
Astellas Pharma US, Inc. (Farmingdale, NY)

- Understanding the risks associated with employing this procedure
  - o Cancellation
  - o Amendment
  - o Preclusion of recovery for past damages
- Protocols and procedures for supplemental proceedings

- Defining a substantial new question of patentability (SNQP)
  - o Question of prior art
- Exploring relationship between supplemental proceedings and inequitable conduct
  - o Circumstances in which supplemental reexam can be used as a means to circumvent questions of inequitable conduct
- Failure to disclose - presence of mind
  - o Intent v. mistake – does it make a difference in the findings?
  - o Findings of fraud in aftermath of proceedings and possibility of criminal prosecution
- Materiality

2:30 **Gambit: Utilizing Third Party Prior Art Submissions in the Pre-Issuance Chess Match**

Michelle Lewis
Vice President of Intellectual Property
Molecular Templates (Newark, NJ)

Suzannah Sundby
Partner
Smith, Gambrell, & Russell, L.L.P. (Washington, DC)

Bryan C. Diner
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. (Washington, DC)

This panel session will enhance your understanding how pre-issuance submissions can be used to as pawn pieces in a completely new chess game. As a competitor, grasp how a pre-issuance submission can be used to direct an examiner to weaknesses and vulnerabilities in a patent application and manipulate an applicant to make certain moves and sacrifices. As an applicant, learn how to defend your position and plan for the moves of competitors post-grant and in the marketplace.

- The chess board and rules of the game:
  - o Timing and formal requirements
  - o Patents, applications, and printed publications: anticipatory and obviousness-type prior art; "of potential relevance to the examination", i.e. need not be prior art
  - o A "concise statement of relevance" – How much and what is acceptable
- Playing the game – Competitor moves:
  - o Evaluating the strengths and weaknesses of prior art in one's arsenal
  - o Determining whether to use the entire arsenal of art or keep some for later use during a post-grant proceeding
  - o Submissions that may force narrowing amendments and/or arguments and admissions thereby resulting in narrow claim construction and prosecution history estoppel
  - o Using submissions to attack the sufficiency of the specification to prevent allowable claims to certain subject matter
  - o Planning for future moves – possible claims an applicant may pursue and post-grant proceedings
- Playing the game or walking away – Applicant moves:
  - o Evaluating scenarios in which a pre-issuance submission might actually strengthen rather than weaken an applicant/patentee's position
  - o Analyzing what result your competitor is trying to achieve by the pre-issuance submission
  - o Keeping your moves open and avoiding being manipulated into a corner
  - o Determining whether commenting on a pre-issuance submission is harmful or helpful and whether a copy of the pre-issuance submission should be provided in related applications along with any comments
  - o Making moves to minimize the ability of competitors to submit pre-issuance submissions
  - o Using the pre-issuance submission to evaluate your competitor's products and future R&D

3:30 **Afternoon Refreshment Break**

3:45 **Examining the Ramifications of Patent Reform for Hatch-Waxman Litigation and the Brand/Generic Wars**

Mary Catherine DiNunzio
Head of Global Patent Alliances
H. Lundbeck, A/S (Copenhagen, Denmark)

Lisa Barons Pensabene
Partner
Fitzpatrick, Cella, Harper & Scinto, L.L.P. (New York, NY)

Given the myriad strategic considerations that companies need to take into account prior to engaging in Paragraph IV litigation, the addition of patent reform has further complicated already complex brand/generic wars. Both branded and generic companies are analyzing the AIA to ascertain the effect on Hatch-Waxman ltigation and debating how post-grant review could potentially impact the playing field for life sciences companies. Add the potential for biosimilars litigation into the mix, and this chess match enters three dimensions, representing nothing less than a geometric increase in complexity. In this session, our expert faculty will use hypothetical situations to explore the implications of patent reform for Paragraph IV and biosimilars litigation and provide guidance on what you should be doing now to prepare for the costly and convoluted litigation that is likely to come.

4:30 **Investigating the Changes to Declarations and Assignments and Understanding How These New Provisions Can Be Used to Keep Prosecution on Track**

Kenneth F. Mitchell, Ph.D.
Patent Attorney
AstraZeneca (Wilmington, DE)

Wesley Nichols
Intellectual Property Counsel
Novo Nordisk, Inc. (Princeton, NJ)

- Outlining the revisions to 35 U.S.C. § 118
  - o Eliminating the statement of citizenship requirement
  - o How do these provisions give applicants more time to file the oath or declaration or a substitute statement?
  - o Including an inventor's declaration on an assignment document
- Filing on behalf of inventor w/o showing of refusal or failure to reach an inventor
  - o The difference between a substitute statement and filing by an assignee
- What is "appropriate" in this case under 35 USC § 118?
- Exploring the effects of PTO regulations covering this new section
  - o Do the regulations restrict the statute?
- Determining when you must file a 3.73b form
- Considering the impact of these changes on employment agreements
  - o How should employment agreements' wording change in light of this provision?

5:15 **Conference Concludes**

Workshop B: Friday, January 25, 2013
9:00 – 12:00 (Registration and Continental Breakfast at 8:15)

Interactive Working Group Session: A Hypothetical Invention Being Patented Under the AIA

Nicholas Boivin
Director Intellectual Property Counsel
Cubist Pharmaceuticals (Lexington, MA)

Thomas L. Irving
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
(Washington, DC)

In this highly interactive post-conference session, expert patent attorneys will use a hypothetical scenario to demonstrate the ways in which the AIA is impacting patent prosecution. Our faculty of expert practitioners will present attendees with a model company developing a novel product, and walk them through all of the steps of patenting the invention, highlighting the steps along the way that will be impacted by the AIA. Framing each step as a fork in the road with what will sometimes be a difficult and highly consequential choice, the decision-making process will be open for discussion, allowing attendees to grasp precisely how the AIA will impact:

- Whether to file at all in light of prior user rights
- Examination choices, whether it be prioritized, micro-entity, under the PPH, etc.
- Claim drafting in light of changes to prior art, pre-issuance challenge, and more
- Crafting a written description with enabling disclosure
- Choice in filing date in light of the March 16, 2013 switch
- Ensuring that all claims have priority
- Anticipating challenges post-grant

Who You Will Meet

✓ **Patent Attorneys (in-house and law firm), Intellectual Property Experts, Business Executives and Policy Analysts for:**

- **Biotechnology Companies**
- **Pharmaceutical Companies**
- **International Pharmaceutical Companies**
- **Biopharmaceutical Companies**

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