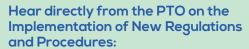


American Conference Institute's 3rd Comprehensive Guide to

Patent Reform

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

January 22–23, 2014 | The DoubleTree Suites by Hilton Times Square | New York, NY



Ms. Janet Gongola (invited)
Associate Commissioner for Patent
Examination Policy
United States Patent & Trademark Office

Hon. James Donald Smith (invited)
Chief Administrative Patent Judge
Patent Trial and Appeal Board
United States Patent & Trademark Office

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Biotechnology Industry Organization
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Preeminent in-house IP counsel, and leading prosecution and litigation attorneys will provide in-depth analysis, practice tips, and guidance on how to adapt your practices to a post-AIA world. Learn about practice pitfalls and new procedural advantages by participating in discussions on such topics as:

- ADAPTING to the first-to-file system and DEVELOPING advanced techniques to ensure issuance of robust patents
- DETERMINING the fate of "best mode", and ANALYZING the pros and cons of utilizing trade secret protection
- INCORPORATING increased due diligence practices pre-issuance to compensate for the expansion of "prior art"
- UTILIZING supplemental re-examination proceedings and PREPARING for third party pre-issuance attacks
- OBTAINING the optimal result in *Inter Partes* Review proceedings
- BRACING for the implementation of Post-Grant Review proceedings, and BENEFITING from Covered Business Methods procedures
- ANALYZING the impact of patent reform on Hatch-Waxman litigation
- SURVEYING and EXPLORING the effects of proposed legislation targeting "non-practicing entities"

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PLUS two interactive Pre- and Post-Conference Workshops:

January 22, 2014:

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

January 24, 2014:

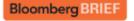
B Interactive Working Group Session: A Hypothetical Invention Being Patented under the AIA

Media Partners:









The America Invents Act is in full effect, and with each passing day the uncertainty surrounding the progress of its implementation decreases. Stay abreast of these developments in order to better prepare for the future.

For the first time in sixty years, the fundamentals of the patent system were overhauled by the America Invents Act (AIA). With such provisions as the expansion of the definition of prior art and creation of a first-to-file system, practice before the Patent and Trademark Office (PTO) has changed from the moment your patent application goes through the door. Numerous parties have taken advantage of the new post-grant proceedings—including inter partes review (IPR), supplemental re-examination, and covered business methods—and the implementation of the post-grant review proceeding looms on the horizon. Develop a plan to deal with the new landscape of the patent system by hearing from practitioners and government officials on the front lines of these changes.

"Know what's weird? Day by day, nothing seems to change, but pretty soon...everything's different." ~ Bill Watterson

American Conference Institute's 3rd Comprehensive Guide to Patent Reform dives into the uncertain waters of the implementation of the AIA and sheds light on its depths by offering insights from senior officials at the PTO, experienced in-house counsel from top innovators, and private practice experts. Our distinguished faculty will discuss such issues as:

- Transitioning to a first-to-file system
- Performing due diligence now that "prior art" has been expanded
- Exploring effective strategies for the new post-grant proceedings
- Analyzing the impact of patent reform on Hatch-Waxman litigation
- Protecting diagnostic methods through detailed patent prosecution

Maximize your ability to protect you or your client's patent portfolio by attending innovative working groups

We are pleased to offer you informative and hands-on workshops which will complete your conference and networking experience:

- Patent Reform 101: A Primer on the Fundamental Provisions of the America Invents Act will provide you with
 an overview of the changes orchestrated by the AIA, setting the necessary framework for the more rigorous
 examinations of strategies and procedures discussed in the main conference
- Patent Litigation Case Law Year in Review—An In-Depth Analysis of Major Cases and Their Effects on Patent
 Eligibility, Enablement, Pleading Requirements, Claim Construction, and More will discuss the landmark decisions
 of the year and those that are pending determination, so that you can stay abreast of the evolution of the industry

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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

WORKSHOP A • JANUARY 22, 2014 • 9:00 – 12:00 (Registration and Continental Breakfast at 8:15 am)



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

David Korn (invited)

Vice President, Intellectual Property and Law Pharmaceutical Research and Manufacturers of America

Robert D. Summers, Jr.

IP Attorney Brinks Gilson & Lione

The America Invents Act (AIA) wrought vast changes on what 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 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
 - First-to-file inventorship
 - Accelerated examination
 - Prior art and pre-issuance
 - Public "disclosure" defined
 - Derivation proceedings
 - Best mode inclusion
- An overview of the litigation and procedural provisions
 - Inter partes review
 - Post grant review
 - Third party prior art submission

- Supplemental examination and reexamination
- Venue, jurisdiction, and procedural matters
- Effect of false marking changes
- · Financial provisions laid out in the AIA
 - Fees and fee setting authority
 - Tax consequences
 - Funding and expenses
- The AIA's impact on universities and academic institutions
 - How the first-to-file system will affect academic innovation
 - How the AIA advantages universities
- · Prioritized examination
 - Determining which technologies can qualify as "important technologies"
 - 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
 - Qualifying as a micro-entity
 - The risks associated with obtaining micro-entity status
 - Fee reduction provisions
- Identifying what was not included in the AIA and the current status of these initiatives
 - 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
 - Applicant Quality Submissions
 - Stays of post-issuance proceedings
 - Limits on injunctions
 - Interlocutory appeals of claim construction

<u>"Exa</u>ctly what I was hoping for – great overview and practice tips." - 2013 Attendee of Patent Reform 101 Workshop

GENERAL SESSION DAY 1 • JANUARY 22, 2014

12:00 Registration

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

Thomas Irving

Partner

1:15

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Donna M. Meuth

Associate General Counsel, Intellectual Property Eisai Inc.

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

Ms. Janet Gongola (invited)

Associate Commissioner for Patent Examination Policy United States Patent & Trademark Office

In this exclusive keynote address, Ms. Janet Gongola will discuss the status of the implementation of the AIA, and how the Patent and Trademark Office (PTO) will operate during the gap years where pre- and post-AIA rules are at play. Ms. Gongola will also discuss the training of its examiners and the various protocols in place to manage patent applications submitted during this tumultuous time. In addition, the representative will provide insight into the dynamics of the pre-issuance period, including analysis of the interplay of disclosures of prior art, third party prior art submissions, and supplemental re-examinations. Finally, the representative will assess the effectiveness of the new "Track 1", prioritized examinations.

2:00 Straddling the First-to-Invent/First-to-File Gap: Changing Company Protocols, Cautiously Approaching Amendments, and Strategies for Promoting Likelihood of Issuance

Adda C. Gogoris

Partner

Merchant & Gould, P.C.

Mercedes K. Meyer, Ph.D.

Partner

Drinker Biddle & Reath LLP



Andrew Paul

Senior Counsel, IP

The Procter & Gamble Company

- · Tools for taking advantage of the race to file
 - Streamlining the internal process of preparing the supporting materials
 - Evaluating when to file a provisional or non-provisional application
 - Determining what constitutes a full or sufficient disclosure—balancing act of breadth and detail of claims
 - Gaining the advantage of secret prior art for eighteen months
- Maintaining a heightened vigilance for third party publications and 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
 - Defining differences between derivation and previous opposition proceedings
 - What are the limitations and benefits of derivation proceedings
 - Proving or disproving that a disclosure was actually derived from the inventor
 - Why is maintenance of meticulous notebook-keeping still important?
- Analyzing the effect of subsequent amendments on pre-AIA submissions
- Utilizing the PTO's Prioritized Examination Program ("Track 1")
 - Knowing the pre-requisites
 - Avoiding procedural pitfalls
 - Advising foreign clients on how to avoid losing priority
- Ethical considerations—the fate of "best mode"
 - If best mode is required under section 112, but has been eliminated as a defense, do you disclose?
 - Does the best mode constitute a trade secret?
 - If foreign client does not disclose best mode, could it lose priority or, worse yet, subsequently be accused of inequitable conduct?
- Filings by non-inventors—analyzing AIA provisions designed to circumvent prior difficulties relating to errant, uncooperative, or missing inventors

Afternoon Refreshment Break 3:30

Through the AIA Prior Art Looking Glass-3:45 Understanding the Global Wonderland of Prior Art, and Utilizing Preissuance Submissions, Supplemental Examination, Ex parte Reexamination, and Reissue

Andrew Baluch

Special Counsel Foley & Lardner LLP

David Dykeman

Shareholder

Greenberg Traurig, LLP

Suzannah Sundby

Partner

Smith, Gambrell, & Russell, LLP

Brian C. Zielinski

Vice President, Assistant General Counsel Pfizer Inc.

- · Adapting to the increased amount of information that can be used as prior art against an applicant
 - Updating prior art searches to include the global wonderland
 - Comparing what constitutes prior art in the US vs. abroad and the risks the differences may pose
 - Determining the implications of AIA-novelty and AIAnonobviousness in the US in comparison to absolute novelty in Europe
- Preparing for the shift to include prior art based on the "effective filing date" and not the date of invention
 - Eliminating the ability to swear back
 - The irrelevance of the Hilmer Doctrine
 - Nonobvious subject matter under post-AIA § 103
- · Applying the 102(b) exceptions to prior art
 - How is the "subject matter disclosed" defined under the regulations?
 - Understanding what constitutes sufficient subject matter identity for 102(b) exceptions and avoiding inadvertent
- · When and what on-sale and public use activities can be considered prior art?
- Attack by third parties Preissuance
 - Grasping the significance of preissuance submissions which allow a third party to direct an examiner to novelty destroying prior art
 - Evaluating the strengths and weaknesses of different kinds of prior art to be used in attacking a patent application
 - Examining scenarios in which the application of a pending patent might actually be strengthened as opposed to diminished by third party submissions
 - Utilizing the ability to respond to a submission by a third party
 - Exploring the impact a response to a third party submission could have on patent term adjustments
 - Investigating ways in which an applicant can anticipate third party submission and take steps to ward off its effects
 - Employing a patent applicant's statements to frame interpretation of claims
 - Using an applicant's statements interpreting claims in other litigation to confine interpretation in a pending application
- New Prior Art Supplemental Examination vs. Ex parte Reexamination vs. Reissue
 - Using supplemental examination, ex parte reexamination, or reissue to cure defects before a patent is challenged
 - Understanding the requirements and risks associated with supplemental examination, reexamination, and reissue
 - Rules and procedures
 - Cancellation
 - Amendment
 - Preclusion of recovery for past damages
 - What constitutes a substantial new question of patentability (SNQP)
 - Ethical considerations—whether to use supplemental examination
 - Circumstances in which supplemental examination can be used as a means to circumvent questions of inequitable conduct
 - Analyzing cases applying Therasense to determine what constitutes inequitable conduct
 - Failure to disclose presence of mind
 - Intent vs. mistake does it make a difference in the findings?
 - Materiality
 - Findings of fraud in aftermath of proceedings and possibility of criminal prosecution
 - Updates on supplemental examinations filed to date and the effects

GENERAL SESSION DAY 2 • JANUARY 23, 2014

8:45 Co-Chair's Opening Remarks

9:00 USPTO Address: Detailing How the New Post-Grant Opposition Procedures Have Impacted Patenting, and Updating on the Implementation of the Post-Grant Review Proceedings

Hon. James Donald Smith (invited)

Chief Administrative Patent Judge Patent Trial and Appeal Board United States Patent & Trademark Office

This exclusive address by Chief Judge James Donald Smith 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. Chief Judge Smith 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 Innovative Practice Resources for Meeting with Success during Inter Partes Review

Kelly K. Burris

Shareholder

Brinks Gilson & Lione

Barbara A. Fiacco

Partner

Foley Hoag LLP

Ralph A. Loren

Partner

Edwards Wildman Palmer LLP

Karl Renner

Principal, Co-Chair of Post-Grant Practice Group Fish & Richardson P.C.

Robert Sterne

Director

Sterne, Kessler, Goldstein & Fox P.L.L.C.

- · Surveying the IPR proceedings filed to date
 - Who is filing and with what result?
 - Has the Federal Circuit weighed in and, if so, to what effect?
 - Is this it as cost effective and efficient as advertised?
- Identifying which patents are most susceptible to IPR
 - Understanding how the proceedings are limited to prior art
 - Determining when to file an IPR during on-going federal litigation
- Preparing for potential IPR review of patents granted prior to November 1999
- What are the discovery rules for IPR?
 - Utilizing the discovery rules to your advantage
 - How and when to use expert witnesses
 - Comparing the scope of what is discoverable—PTAB vs. federal court
- · How do re-issuance proceedings and reexam impact IPR strategy?
- Getting a handle on the burden of proof in IPRs
 - 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

- Patents (prior art) and publications
- Comprehending the relationship between scope of review and estoppel
- Being mindful of subsequent federal litigation—highlighting the bounds of estoppel
 - Knowing what defenses exist outside of the IPR
 - How to avoid becoming a test case
 - Navigating the page limit requirement
 - Participation as a third party on notice
- Transition and phase out
 - Examining the interplay between the timing for post grant review and *inter partes* review
 - Transition in presiding forums
- Choosing between the Central Reexam Unit (CRU) vs. Patent Trial and Appeal Board (PTAB)
 - Appealing to the Federal Circuit

11:15 Morning Coffee Break

11:30 Red Skies on the Horizon—Tracking Developments of Covered Business Method Proceedings and Preparing for the Era of the Post-Grant Review

J. Steven Baughman

Partner

Ropes & Gray

Marc V. Richards

Shareholder

Brinks Gilson & Lione

Moderator:

Peter C. Schechter

Partner

Edwards Wildman Palmer LLP

- Staying abreast of developments relating to Covered Business Method Proceedings (CBM's)
 - Who has been filing?
 - Identifying procedural oddities and practice pitfalls
 - Tracking proposed legislation to expand CBM's to all patent claims
 - Analyzing rulings that have come out to date on such issues as obviousness, enablement, and eligibility
 - Discussing whether CBM's could have precedential effect in other proceedings or federal litigation
 - Strategies or arguments against precedential effect
- 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
 - Is the challenge brought within nine months of patent issuance?
 - 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 from filing the petition to appearing before PTAB
- Analyzing the petitioner's burden of proof
- Procedures for appeal

"Great conference. Well-organized, interesting topics." - 2013 Conference Attendee



12:45 Networking Lunch

2:00 **Examining the Impact of Patent Reform on Hatch-Waxman Litigation and the Brand/Generic Wars**

William Coppola Senior Patent Counsel Sanofi-Aventis

Thomas J. Filarski
Partner
Steptoe & Johnson LLP

Jeffrey Kopacz Senior Patent Counsel Alnylam Pharmaceuticals

Dorothy Whelan

Principal, Co-Chair of Post-Grant Practice Group Fish & Richardson P.C.

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 litigation 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. Topics of discussion will include:

- Exploring the effects of Fresenius v. Baxter
 - Can a jury verdict ever be considered final now?
 - Is it best practice to simply file an IPR at the outset?
 - Can this holding extend beyond verdicts to settlements?
 Is it possible for a generic brand not subject to a "reverse pay settlement" to initiate an IPR?
- Understanding when pre-issuance submission of prior art to the PTO as outlined by this procedure would be used in a Hatch-Waxman scenario
- Examining scenarios in which the application of the pending pharmaceutical patent might actually be strengthened as opposed to diminished by the invocation of third party pre-issuance statements
- Determining when it makes sense for a patent holder in Paragraph IV situations to pursue supplemental reexamination
- Framing the concept of prior art in the pharmaceutical/ biologics context
- Weighing considerations for when a challenge should be brought under PGR in a Hatch-Waxman challenge
- Analyzing the patenting process for drugs and biologics
- Seeking patent protection during the pre-approval process
- IP and regulatory redress for time lost during the pre-approval process
- Distinguishing the patenting process for drugs from that of biologics—which biologics are treated as drugs and why?

3:15 Afternoon Refreshment Break

3:30 Interactive Open Floor Discussion on Proposed Legislation on "Non-Practicing Entities"

Richard Gervase

Member

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

Hans Sauer, Ph.D., J.D.

Associate General Counsel for Intellectual Property Biotechnology Industry Organization

During the years leading up to the AIA, numerous proposals were submitted to include measures to combat alleged "troll" litigation. In the end, the AIA included a non-joinder provision and little else deemed to target this issue. Perhaps the most sensationalized aspect of modern patent litigation, the topic of "patent trolls" has received direct attention from the President, the Chief Judge of the Federal Circuit, a host of legislators, and, as a consequence, the main stream media.

This session will begin with a survey of the pending legislation aimed at this supposed problem, followed by an open discussion on such issues as:

- Do the new proceedings under the AIA affect litigation by "trolls"?
 - Is there a more cost effective method to deal with frivolous litigation with the advent of the IPR, PGR, and other proceedings?
 - Are more "patent assertion" or "non-practicing" entities pursuing these procedures or choosing to remain in federal court?
- What has been the effect of the non-joinder provisions?
 - Have less non-meritorious cases been filed?
 - Has there been a spike in the number of cases reported due to attempts to circumvent this provision?
- · Is legislation needed?
 - What are the potential effects of the different types of legislation? What sort of unforeseen consequences could spill out to all forms of patent litigation?
 - Do the courts and government agencies already have the tools they need to combat frivolous litigation?
 - Should the pleading standard of Form 18 be eliminated?
 - Is a mandatory fee-shifting framework a good idea?

4:30 The Showdown over Diagnostic Methods— Obtaining Patent Protection from the PTO under the AIA Despite the Supreme Court's Nebulous View of a "Product of Nature"

Christopher E. Jeffers, Ph.D.

Attorney at Law Womble Carlyle Sandridge & Rice, LLP

Vineet Kohli

Intellectual Property Counsel GE Healthcare

Bruce S. Weintraub

Senior Corporate Counsel, IP, Legal Division Pfizer Inc.

Not only has the AIA created great uncertainty as to how to proceed with obtaining patent protection, but the Supreme Court has issued rulings in *Prometheus* and *Myriad* that have left life sciences companies, hospitals, and universities looking at their patent portfolios with alarmed confusion. Research and development of diagnostic methods continued during the pendency of *Myriad*, and has continued since its issuance. This session explores the future effects of *Prometheus/Myriad* on diagnostic method patents, and offers advanced techniques in patent application drafting in order to gain patent protection from the PTO.

- Adjudicating patent validity at the PTO
 - Deciding whether to forego the clear and convincing litigation standard in favor of the preponderance of the evidence standard in the PGR process
 - Using reexamination as a tool to challenge or uphold a patent

"Very pleased – timely topics, covered by knowledgeable speakers." - 2013 Conference Attendee

- Factoring in collateral estoppel considerations for claims which should have been raised in the PGR process
- Using IPRs to clear freedom to operate in anticipation of a launch
- · Exploring the confines of Prometheus and Myriad
 - What methods are left unaffected by the rulings?
 - What keywords, such as "isolated", should be avoided in patent applications?
 - Have patent examiners applied these rulings and, if so, how?
- Determining whether a higher concentration of a "naturally" occurring substance qualifies for patent protection

- Analyzing whether reverse engineering products of nature in a laboratory setting runs afoul of Prometheus/Myriad
- Avoiding the slippery slope—applying these and other patent drafting techniques to biosimilars and biologics in order to avoid a Myriad scenario
- Anticipating the interplay between complex patent resolution and new post-grant administrative patent validity proceedings (i.e., IPR, PGR, derivation proceedings, and supplemental re-exams)

5:15 Conference Concludes

WORKSHOP B • JANUARY 24, 2014 • 9:00 – 12:00 (Registration and Continental Breakfast at 8:15 am)



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

Paolo Gerli

European Patent Attorney M. Zardi & Co. S.A.

Thomas Irving

Partner

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Donna M. Meuth

Associate General Counsel, Intellectual Property Eisai Inc.

Clark G. Sullivan

Partner

Troutman Sanders

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. In addition, the speakers will compare and contrast the U.S. system with its international counterparts. 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
- Where to file--advantages and disadvantages to U.S. and international venues
- 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

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American Conference Institute's 3rd Comprehensive Guide to

Patent Reform

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

January 22-23, 2014 | The DoubleTree Suites by Hilton Times Square | New York, NY



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