From **American Conference Institute**, the creator of **Maximizing Pharmaceutical Patent Life Cycles** and **Paragraph IV Disputes**, comes the 3rd San Diego Edition of:

HATCH-WAXMAN BOOT CAMP

ACI'S HATCH-WAXMAN SERIES

A Primer on IP Basics and Regulatory Fundamentals Relative to Small Molecules and Biologics

June 25-26, 2012 | Hilton San Diego Resort & Spa | San Diego, CA

Earn CLE Credits

Gain valuable insights from your distinguished Co-Chairs:

Brian L. Wamsley, Esq.
Patent Attorney
Sandoz, Inc.

Marc T. Morley
Partner
Knobbe Martens Olson & Bear LLP

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Preeminent Patent and FDA lawyers – having a unique understanding of the San Diego/Orange County biopharmaceutical industry – will drill you in the fundamentals of Hatch-Waxman and related IP and regulatory issues as they help you:

- COMPREHEND how recent **biosimilars** legislation is changing industry dynamics
- UNDERSTAND the interplay of between the **PTO** and **FDA** in the patenting of drugs and biologics
- LEARN about the essentials of the **FDA approval process** and its link to biopharmaceutical patents
- DEVELOP an in-depth and practical knowledge of **Hatch-Waxman** protocols, including:
  - **Orange Book listings**
  - **Bioequivalency**
  - **Exclusivities**
  - **The 30-month stay**
  - **The Safe Harbor**
- NAVIGATE the intricacies of **patent term adjustment** and **patent term extension**
- RECOGNIZE how new **pre-commercialization** concerns relative to **CMS** approval and **Medicare/Medicaid formulary selection** are **influencing** the **patenting** and **approval** of **drugs and biological products**

June 27, 2012

Post-Conference Interactive Biosimilars Strategy Session
Biosimilars: An In-depth Look at the Law, Interpreting Regulations, and Anticipated Litigation

Post-Conference Workshop
Patent Reform 101: Overview of the Fundamental Provisions in the America Invents Act and the Impact on Hatch-Waxman Litigation

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ACI's

HATCH-WAXMAN

S E R I E S

For the last decade, **ACI** has been at the forefront of bringing legal counsel and business executives for both brand name and generic pharmaceutical companies the finest programs to address the industry's most pressing Hatch-Waxman challenges. **ACI**'s Hatch-Waxman series provides thoughtful analysis and practical solutions which will help you decipher the complexities of life cycle management, comprehend related policy considerations, and devise strategies and perfect trial advocacy skills for Paragraph IV litigation.

ACI'S HATCH-WAXMAN SERIES ADVISORY BOARD

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About SDIPLA

SDIPLA
The San Diego Intellectual Property Law Association

SDIPLA has grown to over 475 registered members. Thanks to the dedication and leadership of past Board members, the SDIPLA has grown to be among the largest intellectual property bar organizations in the country.

A primary goal of the SDIPLA is to continue our long-standing tradition of providing valuable continuing legal education to our members by securing top-quality, nationally recognized speakers to address the most current issues in intellectual property law.

Who You Will Meet:

In-house counsel and executives from pharmaceutical, biotech & biopharmaceutical companies, including:

- Patent attorneys
- Patent agents
- FDA & regulatory attorneys
- Officers & directors for
  - Business development
  - R&D
  - Strategic alliances
  - Regulatory affairs

Law firm attorneys for the pharmaceutical, biotech & biopharmaceutical industries whose practices focus on:

- Patent prosecution
- Patent litigation
- IP
- Life sciences transactions
- FDA and food & drug law

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ACI, along with our sister organization based in London, **C5** Conferences, works closely with sponsors in order to create the perfect business development solution catered exclusively to the needs of any practice group, business line or corporation. With over 350 conferences in the United States, Europe, the Commonwealth of Independent States (CIS) and China, **ACI/C5** Conferences provide a diverse portfolio of first-class events tailored to the senior level executive spanning multiple industries and geographies.

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Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

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You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and **ACI** will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

ACI, the nation's premier provider of life sciences intellectual property conferences, is pleased to bring the third west coast installment of its renowned Hatch-Waxman Series back to San Diego.

2011 brought the enactment of the America Invents Act and 2012 marked the release of the FDA Draft Guidance on Biosimilars. Understand how this will impact the Hatch-Waxman arena.

Now in its third year, Hatch-Waxman Boot Camp – San Diego Edition has become the gathering place of the Southern California life sciences IP Bar. With the precedential regulatory changes in the IP regulatory arena there will clearly be impacts to Hatch-Waxman. Attend this essential event to understand the interplay of IP and FDA regulation relative to pharma/biotech patents vis-à-vis Hatch-Waxman and recently released biosimilars guidance and ensure that you are aware of the intersection of the newly promulgated America Invents Act with Hatch-Waxman. It is vital to understand how all these components work together and that both will influence the Hatch-Waxman rubric.

A thorough understanding of Hatch-Waxman is absolutely essential to anyone working in the biopharmaceutical area. This knowledge sets the foundation for the protection of small molecules and small proteins and provides the tools to ponder an IP and regulatory framework for what lies beyond the realm of traditional pharmaceuticals. The highly regulated nature of the products which the pharmaceutical and biotechnology industries manufacture dictates that the patenting of these products be closely tied to regulatory approval by the FDA. Anyone who works in the life sciences industry – and who even remotely deals with its IP – must be well versed in the regulatory components and IP subtleties that play such an integral role in the patenting of its products.

You cannot afford to be left in the dark regarding the interconnection of IP and FDA regulation in these industries.

Gain the competitive edge – boost your life sciences IP and regulatory IQ.

ACI's **Hatch-Waxman Boot Camp** has been designed to give counsel and advisors to brand name and generic drug companies – and biopharmas – critical insights into commercialization and the pre-approval process, and also provide you an in-depth review of Hatch-Waxman and other IP basics relative to small molecules and biologics. This conference will lay the necessary foundation for you to thoroughly comprehend the dynamics of the applicable patent life cycles for pharmaceutical and biopharmaceutical products and business development plans.

Master the intricacies of the patent and regulatory framework for drugs and biologics.

A faculty of top-notch IP and regulatory counsel – all having a wealth of experience through working for brand names and generics as well as biopharmas – will share their knowledge on:

- The organization, jurisdiction of the FDA and the PTO and their interplay in the patenting of drugs and biologics
- How the approval process for drugs and biologics is connected to the patenting of these products
- Pre-patent considerations relative to R&D and patent portfolio and patent life cycle management
- How the Hatch-Waxman Act established the paradigm for market entry of generic small molecule drugs – and how biosimilar products are adding a new dimension to this schematic
- The relationship between patent and non-patent exclusivity
- The importance of patenting bioequivalence characteristics in certain drug products
- The ins and outs of patent term extension under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791

Also, in response to your requests, we have added a special **Interactive Biosimilars Strategy Session**, which will provide an overview of the law governing biosimilars and will then delve into interactive hypotheticals about the inner-workings of the BPCIA and anticipated litigation scenarios.

New for 2012 is a post-conference workshop **Patent Reform 101: Overview of the Fundamental Provisions in the America Invents Act and the Impact on Hatch-Waxman Litigation**, which will walk you through the AIA and highlight important aspects of the Act vis-à-vis Hatch-Waxman, including understanding the implementation schedule for certain provisions of the Act.

Attend this conference and learn to navigate your way through the IP and regulatory mazes that play such a crucial role in your practice areas. Register now by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or registering online at **www.AmericanConference.com/HWBootCamp**

DAY ONE: JUNE 25, 2012

8:00 **Registration and Continental Breakfast**

9:00 **Co-Chairs' Opening Remarks**

Brian L. Wamsley, Esq.
Patent Attorney, Sandoz, Inc. (Princeton, NJ)

Marc T. Morley
Partner, Knobbe Martens Olson & Bear LLP
(San Diego, CA)

9:15 **Key Agencies Overview: Understanding the Jurisdiction and Interplay of the FDA and PTO in the Patenting of Drugs and Biologics**

Elaine Tseng
Partner, King & Spalding LLP (San Francisco, CA)

- Understanding the respective roles and interplay of the FDA and PTO in the patenting and approval of drugs and biological products

FDA

- FDA overview and organization
  - Department of Health and Human Services and the Commissioner
  - The 5 FDA Centers and the Office of Regulatory Affairs and their functions
- CDER (Drug) and CBER (Biologic) overview
- Defining the scope of the FDA's jurisdiction with respect to drugs and biologics
- Examining how the FDA exercises its jurisdiction:
  - rule making; product decisions; enforcement; informal mechanisms
- Reviewing the laws that the FDA enforces relative to the patenting of drug and biological products
  - Food Drug & Cosmetic Act; Prescription Drug Marketing Act; Public Health Services Act; Hatch-Waxman Act; other applicable laws
- Defining drugs and biologics
- Labeling: when is a drug a drug and not a biologic
- Working with the FDA
  - Administrative Procedures Act
  - formal and informal dispute resolution mechanisms

The PTO

- Review of the organizational structure of the PTO
- Patents: overview of drug and biological products that may be patented
- Who may apply for a patent?
  - agency and inventorship
- What is the PTO's jurisdiction in the patenting of drugs and biologics?
- What laws and regulations does the PTO enforce relative to the patenting of drugs and biologics?
- Patent Reform Legislation
- Trademark and copyrights vis-à-vis drugs and biologics

10:15 **Morning Coffee Break**

10:30 **Identifying and Comprehending Pre-Commercialization Concerns Relative to Small Molecules and Biologics**

Edward J. Allera
Partner, Buchanan Ingersoll & Rooney, P.C.
(Washington, DC)

The current pre-commercialization landscape:

- Reviewing the types of products that pharmaceutical, biotechnology and biopharmaceutical companies seeking to develop now
- Identifying impediments – through patent or regulatory restraint – which prevent these companies from pursuing the development of the desired product
  - FDA hurdles that may not clear even if all patent and other IP hurdles are met
- Techniques for analyzing the value the product adds to the company's portfolio, and methods for proving value
- Assessing the competition and analyzing potential therapeutic interchange considerations

Considerations in light of Health Care Reform:

- Understanding how the introduction of biosimilars is changing the commercial landscape
- Examining the role of the Center for Medicare and Medicaid Services (CMS) in the approval process and its impact on R&D
  - the connection between CMS approval and commercial viability via government payor systems and rebates
  - comparative effectiveness

11:15 **Exploring the Link between the FDA Approval Process and the Patenting of Drugs and Biologics**

Anders T. Aannestad
Partner, Morrison & Foerster LLP (San Diego, CA)

Richard Berman
Partner, Arent Fox LLP (Washington, DC)

Rx Drugs (new drugs)

- Identifying the application process for the approval of a new drug, i.e., small molecule, new chemical entities, etc.
- NDA (New Drug Application): definition, contents and regulatory overview
- INDA (Investigational New Drug Application) aka "IND"
  - how does it differ from an NDA?
- Accelerated approvals
  - defining eligibility criteria for accelerated approval and priority reviews
- Using advisory committees in the approval process

Biologics

- How does the approval process for a biologic differ from that of a drug?
- BLA (Biological Licensing Application): application and filing
  - how does a biologic differ from a drug?
  - which products require BLAs instead of NDAs?
- Why is it a "license," rather than an "approved application"?

12:15 **Networking Luncheon**

1:30 **IP Overview for Drugs and Biologics: Hatch-Waxman, BPCIA, Trade Dress, and More**

Marc T. Morley
Partner, Knobbe Martens Olson & Bear LLP
(San Diego, CA)

IP Protection for Drugs and Biologics

- 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?
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

Drugs
- Exploring the differences between a NDA and an ANDA (Abbreviated New Drug Application)
- ANDA: what does it require?
- Bioequivalence defined
- The Orange Book: what is it and why is it Orange?
  - listings and de-listings

Biologics
- Understanding draft biosimilars guidance released by the Food and Drug Administration
  - formulations, routes of administration, and indications
  - interchangeability
  - new regulatory definitions
- Identifying biologics that fall within the purview of Hatch-Waxman
- The rationale for safety and efficacy concerns surrounding second generation biologics

Trademark Issues
- Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product

2:45 **Paragraph IV Disputes and Litigation: Federal Court, PTO Proceedings & ITC Actions**

Robert J. Goldman
Partner, Ropes & Gray LLP (East Palo Alto, CA)

Herbert D. Hart III
Shareholder, McAndrews, Held & Malloy, Ltd. (Chicago, IL)

Vicki Norton
Partner, Duane Morris LLP (San Diego, CA)

District Court (Traditional Paragraph IV Litigation)
- Paragraph IV Certifications and Notice Letters
- Presuit considerations
  - Initial pleadings; Multiple ANDA filers; Declaratory judgments
- The patent endgame (Hatch-Waxman Overview)
  - overview of Hatch-Waxman and reforms under MMA
  - the role of Orange Book under Hatch-Waxman vis-à-vis the MMA
  - exclusivity (180 day); 30-month stay; patent extensions; the safe harbor
- Typical Paragraph IV litigation scenarios
  - "invalid or will not be infringed"
- Hot button issues in Hatch-Waxman litigation
  - settlements; damages; double-patenting; inducement of infringement
- FD&C 505b2 (an alternate pathway to an ANDA)

Applicable PTO Proceeding Under the America Invents Act
- Understanding the fundamentals of the AIA and it's procedures
- Identifying how the AIA intersects with the Hatch-Waxman rubric
  - supplemental proceedings
  - Third party pre-issuance submission

Post Grant Review
- Should you challenge an OB-listed patent by petitioning for a post grant review (PGR)?
- What are the relevant considerations?
  - Would a challenge be timely?
  - Is the basis of the invalidity challenge one suited for resolution in a PGR proceeding?
  - prior art (anticipation and/or obviousness)
  - § 112 insufficient written description or lack of enablement
  - basis of the invalidity challenge; timing; prior art; 112 deficiency under written description; lack of enablement; o obviousness; inherent anticipation; fate of best mode
- Estoppel considerations relative to Paragraph IV litigation
- What are the mechanics, protocols, and procedures for PGR?
  - Is a PGR proceedings analogous to district court litigation?
  - What will the procedures be?
  § the petition
  § discovery
  § hearings; motions; settlement
  - The Patent Trial and Appeal Board (PTAB)
- Analyzing the petitioner's burden of proof
- Procedures for appeal

Inter Partes Review
- Comparing current inter partes reexamination protocols to inter partes review protocols under AIA
- Examining how current inter partes reexamination procedures are being employed by both patent challengers and patent holders in Hatch Waxman scenarios
  - questions of economics, efficiencies and risk
- Understanding the fine points of the new inter partes review procedure
  - considerations for choosing this forum
  - timing, cost, speed of resolution
- Revisions to patent challenger's burden of proof under current inter partes reexamination and new inter partes review procedures
  - 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
- Transition and phase out
  - examining the interplay between the timing for post grant review and inter partes review
  - Central Reexam Unit (CRU) vs. Patent Trial and Appeal Board (PTAB)
  - appeal to CAFC

4:00 **Afternoon Refreshment Break**

4:15 **How the Dynamics of Biosimilars Are Changing the Hatch-Waxman Landscape**

Madison Jellins
Partner, HelixIP LLP (Redwood City, CA)
- What are biologic drugs and why are they different for purposes of generic competition?
- When can FDA approve a biosimilar under current law?
- What kind of abbreviated approval route for biologics is available under the new Act?
- Exploring concerns over:
  - exclusivity; patentability; interchangeability

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

DAY TWO: JUNE 26, 2012

8:00 **Continental Breakfast**

8:45 **Co-Chairs' Opening Remarks and Re-Cap of Day One**

9:00 **Orange Book Listings, De-Listings and Related Challenges**

Kurt R. Karst
Director, Hyman, Phelps & McNamara, P.C.

Ellen A. Scordino
Principal, Fish & Richardson P.C. (Boston, MA)

- Understanding the role of Orange Book listings in patent life cycle management and patent portfolio management
- Exploring the continuing dilemma of which patents should be listed, delisted and held in reserve
- Assessing the effect of de-listing/disclaiming a patent on 180-day exclusivity
- Examining the FDA's position on not listing a patent
- Overcoming challenges associated with listing patented information in the product label and indications discovered in clinical testing
  - incorporating long term patent listing strategies into label negotiations with FDA
  - skinny labeling and carve-outs
- Reviewing antitrust considerations relative to Orange Book listings
- Assessing the scope of potential Orange Book listing controversies relative to:
  - device patents; product-by-process claims; metabolites; polymorphs; intermediates; patents on unapproved uses; old antibiotics under QI Act; use codes

10:00 **Morning Coffee Break**

10:15 **Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability**

Peter Munson
Partner, Wilson Sonsini Goodrich & Rosati LLP (San Diego, CA)

- Defining bioequivalence in drugs and biologics
  - drugs v. biologics
- What an ANDA-filer must demonstrate for bioequivalence?
  - bioequivalence and dosage form – oral tablet/capsule, injection, nasal sprays, topical, nasal sprays
- How does bioequivalence relate to patents?
  - patenting of bioequivalence characteristics – extended-release drug products
  - bioequivalence v. Doctrine of Equivalents – what is the difference?
  - arguments about bioequivalence raised in Paragraph IV patent litigation
    - o infringement, copying (non-obviousness)

11:15 **An In-Depth Look at 180-Day Exclusivity**

David G. Adams
Partner, Venable LLP (Washington, D.C.)

Brian L. Wamsley, Esq.
Patent Attorney, Sandoz, Inc. (Princeton, NJ)

- Understanding 180-day generic market exclusivity under the Hatch-Waxman Act
  - what are the qualifying criteria for exclusivity?
- How can an ANDA applicant really determine who is "first-to-file" and win 180–day exclusivity?
- Identifying triggers for the running of the 180-day exclusivity period
- Deciphering the FDA's new interpretation of pre- and post- MMA 180 day exclusivity
  - what are the implications of this interpretation for products having ANDA's filed prior to the enactment of the MMA?
- Exploring the interplay between the 30-month stay and 180-day exclusivity
  - what steps must be taken when a Paragraph IV certification is issued?
- Forfeiture provisions: identifying circumstances under which exclusivity is forfeited
  - Other circumstances that may trigger the loss of 180-day exclusivity
- When can the 180-day exclusivity period be transferred to another ANDA applicant?
- Evaluating when the 180-day exclusivity period can be relinquished, and exploring the consequences
- Defining "shared exclusivity"
- Case law update
  - Vyvanse (Actavis v. FDA); Sanofi v. Apotex

12:15 **Networking Luncheon**

1:30 **Comprehending the Intricacies of Non-Patent/ Regulatory Exclusivity**

George Ng
Partner, Snell & Wilmer LLP (San Diego, CA)

Len Smith
Principal Intellectual Property Counsel
Medicis Pharmaceutical Corp. (Scottsdale, AZ)

- Understanding which drug products are eligible for regulatory exclusivity
  - small molecules v. biologics
- The different modes and methods of regulatory exclusivity (non-patent)
  - NCE (new chemical entity): 5 years marketing exclusivity/5 years data exclusivity
  - indication (new indication or use): 3 years marketing exclusivity
  - NDF (new dosage formulation)
  - ODE (orphan drug exclusivity)
  - PED (pediatric exclusivity)
- FD&C 505b2 (alternate pathway to ANDA) a/k/a paper NDA
- What role does the FDA play in regulating these modes of exclusivity?
- When are each of these methods sought?
- Using trade dress as means of exclusivity

2:30 **Afternoon Refreshment Break**

2:45 **Assessing Patent Protections Afforded Under the Safe Harbor**

Robin M. Silva
Partner, Morgan Lewis & Bockius LLP (San Francisco, CA)

- Exploring the safe harbor of the Hatch-Waxman Act 35 USC § 271(e)(1)
- Understanding the safe harbor's scope of protection for otherwise infringing activities
- Examining the impact of Proveris on safe harbor protections afforded to research tool patents
- Identifying safe harbor protections relative to:
  - basic R&D; new product screening; optimization; pre-clinical testing; post-approval testing

3:30 **Examining Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration**

Louis C. Cullman
Partner, K&L Gates LLP (Irvine, CA)

- Extension of patent term under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791

- Exploring the viability of extension applications to:
  - basic and combination compounds; secondary patents
- Important benchmarks in the drug's development and patent timelines
- Eligibility for patent term extension
- Regulatory review period determinations
- How to calculate the patent term restored
  - respective roles of the FDA and PTO in granting patent extensions
  - third-party challenges – "diligence"
- Patent term extensions outside the U.S.
- Evaluating PTO letters interpreting judicial guidance
  - *Photocure ASA v. Kappos*
  - *Ortho-McNeil Pharmaceutical, Inc. v. Lupin Pharmaceuticals, Inc.*
- Examining patent term adjustment due to delays in prosecution before the USPTO
  - strategies for:
    - o diligence in prosecution by the patent applicant
    - o calculating the adjustment period
- Understanding the link between patent extensions and exclusivity
  - extensions obtained through FDA Pediatric Exclusivity and Orphan Drug Exclusivity
- Obtaining patent coverage for pharmaceuticals through the use of second-generation patents, e.g.,
- Assessing the impact of the PTO Rule regarding elimination of continuation practice on pharmaceutical patent extensions

4:45 **Conference Concludes**

A POST-CONFERENCE INTERACTIVE BIOSIMILARS STRATEGY SESSION

June 27, 2012 • 9:00 a.m. – 12:00 p.m. *(Registration begins at 8:30)*

Biosimilars: An In-Depth Look at the Law, Interpreting Regulations, and Anticipated Litigation

Elaine Tseng
Partner, King & Spalding LLP (San Francisco, CA)

This strategy session will provide an overview of the law governing biosimilars and will then delve into the preparations that should be made in anticipation of litigation. Building on the foundation of the law, the workshop will shift into a hypothetical scenario in which the inner-workings of the statute will be explored in-depth, and the class will run through what the first biosimilars litigation could possibly look like.

A team of experts will lead you through every facet of this exciting and challenging new area. Points of discussion will include:

- Identifying major provisions of the act
- Preventing major mistakes early by determining which patents must be named in the generic certification process
  - What happens if you omit listing a patent that should be listed?
  - Is an omitted listing tantamount to forfeiting the right to sue on it?
- Examining the legislation with respect to:
  - proposed pathways; exclusivity and the interpretation of that word; patentability; interchangeability; no Orange Book listing
- Assessing the similarities and differences between Hatch-Waxman and how a Hatch-Waxman model will compare to an exclusivity model designed for biological products
- Understanding the Act's impact through early FDA guidelines and requirements
- Abbreviated approval process differentiations for small v. large proteins
- An update on biosimilars in Europe

Media Partners:

B POST-CONFERENCE WORKSHOP

June 27, 2012 - 1:00 p.m. – 4:00 p.m. *(Registration begins at 12:30)*

Patent Reform 101: Overview of the Fundamental Provisions in the America Invents Act and the Impact on Hatch-Waxman Litigation

George Ng
Partner, Snell & Wilmer LLP (San Diego, CA)

Ellen A. Scordino
Principal, Fish & Richardson P.C. (Boston, MA)

Given the vast complexities laid out in the AIA, it is necessary to have a basic working knowledge of the multiple provisions in the AIA. In this interactive primer, the expert speakers will provide you with a clear overview of the numerous sections in the Act, especially highlighting how it will tie into Hatch-Waxman and when implementation will begin. Topics of discussion include:

- Definitions in the Act explained
- Outlining the provisions impacting prosecution
  - First inventor to file
  - Prior art and preissuance
  - Derivation proceedings
- An overview of the litigation and procedural provisions
  - Inter partes and post grant review
  - Supplemental examination and reexamination
  - Venue, jurisdiction and procedural matters
  - Joinder of parties
  - False marking
- Financial provisions laid out in the AIA
  - Fees and fee setting authority
  - Tax consequences
  - Funding and expenses
- Changes to Patent Term Extension calculations
- Studies and satellite offices
- 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 the Therasance and the impact of changes to supplemental examinations in the AIA on inequitable conduct
  - The continuing brewing saga over limiting damages in patent infringement cases
  - The dreaded Applicant Quality Submissions
  - Stays of post-issue proceedings
  - Limits on injunctions
  - Interlocutory appeals of claim construction

From **American Conference Institute**, the creator of **Maximizing Pharmaceutical Patent Life Cycles** and **Paragraph IV Disputes**, comes the 3rd San Diego Edition of:

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☐ I would like to receive CLE accreditation for the following states: _____. See CLE details inside.

FEE PER DELEGATE	Register & Pay by Apr 27, 2012	Register & Pay by May 25, 2012	Register after May 25, 2012
☐ ELITEPASS*: Conference & Both Workshops	$2995	$3095	$3295
☐ Conference & Post-Conference Workshops ☐A or ☐B	$2595	$2695	$2895
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**ELITEPASS is recommended for maximum learning and networking value.*

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☐ I have enclosed my check for $_____ made payable to **American Conference Institute** (T.I.N.—98-0116207)

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Bank Name: HSBC USA
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Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

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Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI** reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **ACI** for changes in program date, content, speakers, or venue.

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Incorrect Mailing Information

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5 Easy Ways to Register

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