From **American Conference Institute**, the creator of **Maximizing Pharmaceutical Patent Life Cycles** and **Paragraph IV Disputes**, comes the Chicago 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 9 – 10, 2014 | InterContinental Chicago Magnificent Mile | Chicago, IL

Gain valuable insights from your distinguished Co-Chairs:

Thomas Filarski
Partner
Steptoe & Johnson LLP (Chicago, IL)

Jason G. Winchester
Partner
Jones Day LLP (Chicago, IL)

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

- 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
  - Paragraph IV litigation introduction
- NAVIGATE the intricacies of patent term adjustment and patent term extension
- COMPREHEND how the BPCIA biosimilars pathway for large molecules will compare to the Hatch-Waxman schematic for small molecules

June 11, 2014 | Post-Conference Interactive Biosimilars Strategy Session
Biosimilars: The Law, Interpreting Regulations, and Anticipated Litigation

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Jason G. Winchester
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ACI, the nation's premier provider of life sciences intellectual property conferences, is pleased to announce that the primer course in its Hatch-Waxman Series is coming to Chicago

Understand the interplay of IP and FDA regulation relative to pharma/biotech patents vis-à-vis Hatch-Waxman

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.

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

Redesigned as a true training program and taught by preeminent authorities in the pharmaceutical patent bar, **ACI's Hatch-Waxman Boot Camp – Chicago** will provide the fundamentals of practicing in the Hatch-Waxman space to attorneys who are new to this area. Additionally, this program will be of great benefit to in-house business development executives, government affairs officers, and others to whom a working knowledge of the Hatch-Waxman schematic is a critical competency to fulfill their job functions.

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 and 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 the BPCIA may establish a new paradigm for themarket entry of biosimilars
- 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

To complete your conference experience, attend the **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.

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**

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

Day One: June 9, 2014

8:00 Registration and Continental Breakfast

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

Thomas Filarski
Partner
Steptoe & Johnson LLP (Chicago, IL)

Jason G. Winchester
Partner
Jones Day LLP (Chicago, IL)

9:15 **KEY AGENCIES OVERVIEW: Understanding the Jurisdiction and Interplay of the FDA and PTO in the Patenting of Drugs and Biologics**

Dorothy R. Auth, Ph.D.
Partner
Cadwalader, Wickersham & Taft LLP (New York, NY)

Marc T. Morley, Esq.
Partner
Foley & Lardner LLP (San Diego, 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 **Exploring the Link between the FDA Approval Process and the Patenting of Drugs and Biologics**

Adam Samansky
Partner
Edwards Wildman (Boston, MA)

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
  - what portions of approval submissions might FDA release and when?
- 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"?

Biosimilars

- What does the approval process for a "biosimilar" entail?
  - how is it different from the BLA approval process?

11:30 **IP Overview for Drugs and Biologics: Hatch-Waxman, BPCIA, Trade Dress, and More**

Patricia Carson
Partner
Kirkland & Ellis LLP (New York, NY)

Bruce C. Haas
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

Michael Siem
Partner
Farney Daniels, P.C. (Brooklyn, NY)

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
- 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
  - regulatory exclusivity
  - patent extensions
  - the safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

Biologics

- Identifying biologics that fall within the purview of Hatch-Waxman
  - why are other biologics outside of the Hatch-Waxman rubric?
- Overview of the Biologics Price Competition and Innovation Act of 2009 (BPCIA), *i.e.*, biosimilars legislation
  - status of pending FDA guidance and regs
  - the rationale for safety and efficacy concerns surrounding second generation biologics

Trademark, Trade Name and Trade Dress Issues

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

1:00 Networking Luncheon

2:15 **ANDA Litigation 101: Paragraph IV Disputes Primer**

Thomas Filarski
Partner
Steptoe & Johnson LLP (Chicago, IL)

Gregory Morris
Of Counsel
Paul Hastings LLP (Chicago, IL)

Jason G. Winchester
Partner
Jones Day LLP (Chicago, IL)

- Paragraph IV Certifications and Notice Letters
- Presuit considerations
  - initial pleadings
  - multiple ANDA filers
  - declaratory judgments
- 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

3:30 Afternoon Refreshment Break

3:45 **Orange Book Listings, De-Listings and Related Challenges**

Jonathan E. Grossman
Patent Attorney
Fresenius Kabi USA (Lake Zurich, IL)

Kurt R. Karst
Director
Hyman, Phelps & McNamara, P.C. (Washington, DC)

Shashank Upadhye
Partner
Seyfarth Shaw LLP (Chicago, IL)

- 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

5:00 Conference Adjourns to Day Two

Day Two: June 10, 2014

8:00 Continental Breakfast

9:00 **Co-Chairs' Opening Remarks and Re-Cap of Day One**

9:15 **Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability**

Gary J. Speier
Partner
Schwegman, Lundberg & Woessner, P.A.
(Minneapolis, MN)

Gary Veron
Partner
Hogan Lovells US LLP (Washington, DC)

- 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
- Exploring bioequivalence controversies related to biosimilars
- 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)

10:15 Morning Coffee Break

10:30 An In-Depth Look at 180-Day Exclusivity

Reka Hanu
Counsel Intellectual Property
Akorn Pharmaceuticals (Lake Forest, IL)

Scott B. Howard
Partner
Patterson Belknap Webb & Tyler LLP (New York, NY)

- 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"

11:30 Comprehending the Intricacies of Non-Patent/ Regulatory Exclusivity

John E. Haugen
Senior Counsel, IP
Takeda Pharmaceuticals U.S.A., Inc. (Deerfield, IL)

- 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

12:30 Networking Luncheon

1:45 Assessing Patent Protections Afforded Under the Safe Harbor

Brian Coggio
Senior Principal
Fish & Richardson (New York, NY)

Paul S. Tully, PhD
Partner
McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

- 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*, *Classen* and *Momenta* on safe harbor protections
- Identifying safe harbor protections relative to:
  - basic R&D
  - new product screening
  - optimization
  - pre-clinical testing
  - post-approval testing

2:45 Afternoon Refreshment Break

3:00 Examining Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration

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

- Overview of Patent Term Adjustment (PTA)and Patent Term Extension (PTE)
  - statutory authorities
    - o Patent Act
    - o Hatch-Waxman Act
- Understanding the unique role of PTA and PTA in the longevity of patent life cycles in the life sciences industries
- PTA vs. PTE
  - seeking redress for PTO delays vs. seeking redress for FDA delays
- Which point of patent life does each of these devices extend?
  - full scope of patent vs. full scope of patent life of patented product

PTA

- Review of 35U.SC. 154(b) and 37 C.F.R. 1.702 -1.705
- Comprehending the criteria for PTA eligibility
- Reconciling discrepancies in certain PTA and PTO Rules
- Seeking PTA
  - starting point and the Notice of Allowance
  - addressing dispute with PTO's initial PTA calculation request for Reconsideration /Application for Correction
  - when can PTA be corrected after the issuance of the patent
- PTO delays v. applicant delays
- A, B and C-delays and overlaps
- RCE- Request for Continued Examination

PTE

- Overview of PTE
  - 35 USC 156
  - 37 CFR 1.710 – 1.791
- Identifying important benchmarks in a drug's development and patent timelines relative to seeking PTE
  - what is the patent term restored and to what does it apply?
    - o defining "drug product" under PTE provisions of Hatch-Waxman Act
      - salts
      - esters
      - enantiomers
  - regulatory review period determinations
    - o testing phase
    - o review phase
- Understanding why PTE provisions in the Hatch-Waxman Act extend to products outside the scope of Hatch-Waxman, *i.e.*, biologics and certain medical devices
  - the importance of PTE in a biosimilars scenario
- Reviewing eligibility requirements/prerequisites for patent term extension
- Calculating the patent term restored
  - FDA/ PTO interplay
- Criteria and eligibility for interim extensions

4:00 Conference Concludes

Post-Conference Interactive Biosimilars Strategy Session
June 11, 2014 | 9:00 AM – 12:00 PM (Registration begins at 8:30 AM)

Biosimilars 101: Interpreting the Law, Appreciating the Science, Anticipating Regulations and Preparing for Litigation

This strategy session will provide an overview of the law and science governing biosimilars and will then delve into the preparations that should be made in anticipation of litigation. Biosimilars litigation is uncharted territory, as such actions are still theoretical. This session will not only take a look at the approval process and differentiate it from the BLA process, but will also run through hypothetical scenarios of what litigation will look like.

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

- Overview of the 2010 Biologics Price Competition and Innovation Act (BPCIA)
  - exclusivity provisions
  - criteria for biosimilarity and interchangeability
  - clinical trials and safety studies
  - patent litigation and exchange provisions: understanding the major differences between Hatch-Waxman and biosimilars litigation as outlined in the statute
- What attorneys need to know about the science of biologics and biosimilars
  - key differences between drugs and biologics
  - living organisms versus chemically synthesized molecules
- Identifying types of biologics which may be ripe for a biosimilar applications: monoclonal antibodies, therapeutic proteins, and vaccines
- Comparing and contrasting the biosimilar pathway to 505(b)(2) v and BLA pathways
  - determining whether research and development resources are best spent pursuing a biosimilar pathway or going the traditional BLA route
  - breakdown of relevant considerations with each route including timing, costs, and IP litigation considerations, and exclusivity
- Anticipating how the 12 year exclusivity proposed by the Trans-Pacific Partnership (TPP) trade agreement will interact with biosimilars statutory exclusivity
- Recapping the statements and guidance issued by FDA post-BPCIA: what are the open questions and when is final guidance expected?
- Update on the closed door meetings between manufacturers and FDA and the case-by-case review: anecdotal tales of the FDA's "totality of the evidence" approach
- Breakdown of applicable state biosimilars bills affecting substitution
- Substituting the biosimilar at the pharmacy level: what will it take to make interchangeability possible?
  - methods for demonstrating safety and efficacy in a biosimilar product
  - structuring clinical trials and safety studies
- Defining the term "biobetter" and choosing whether to seek pure "biosimilarity" or an improved "biobetters" product or both
- Survey of key cases and legal developments impacting biosimilars
  - *Sandoz v. Amgen* – the first BPCIA case
  - *Momenta v. Amphastar* and the safe harbor
  - Abbott Citizen's Petition: is retroactively applying a new set of laws an unconstitutional taking?
- An update on biosimilars in Europe
  - what can the US glean from Europe with respect to the introduction of these products into the European market?
  - a review of interchangeability requirements in the EU

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POST-CONFERENCE INTERACTIVE BIOSIMILARS STRATEGY SESSION

Biosimilars: The Law, Interpreting Regulations, and Anticipated Litigation

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