Preeminent members of the U.S. regulatory and patent bar will help you formulate a plan for the first wave of U.S. biosimilars and will provide:

**Regulatory Insights:**
- USFDA’s current initiatives regarding the first wave of biosimilars applications
- Discussion of the USFDA review panel and approval of Sandoz’s Filgrastim biosimilar
- Status of final USFDA biosimilars guidance
- Analysis of USFDA standards for biosimilarity, interchangeability, and clinical studies

**Intellectual Property insights:**
- A cheat sheet for managing the complicated litigation timeframes under the BPCIA
- Reviewing the biosimilars litigation cases to date including Sandoz v. Amgen and Celltrion v. Janssen
- Strategies for declaratory judgment actions, preliminary injunctions, and using new USPTO inter partes review procedures

**Competition Insights:**
- Exploring the key players and alliances to date in the nascent U.S. market
- Update on the battles for substitution at the pharmacy and naming conventions
- Understanding the role of the Federal Trade Commission (USFTC) in protecting biosimilars competition

**Maximize Your Conference Participation – see page 3:**

**Biosimilars 101: Essential Training for EU Pharmaceutical Lawyers on the Relevant US Regulatory and Legal Landscape**

Attendees of this full-day session will walk away with an up-to-the-moment treatise on the significant regulatory, IP, and competitive developments affecting US biosimilars, setting the stage for the rest of the conference.
At long last, US biosimilars are a reality. Attend the premier event designed to give global innovator and biosimilar companies clarity on the complex regulatory and patent challenges ahead.

Dear Colleague,

Based on industry demand, ACI is bringing its flagship Biosimilars event to the EU companies who will doing business in the US. As companies are officially moving forward with the first U.S. biosimilar applications, and the USFDA has given its stamp of approval to at least one, hear directly from the best of the US bar about how the major developments in US law will affect you.

The year’s major developments show that the time for speculation and hesitation have passed, and whether you are on the innovator or biosimilar side, you must have a plan for US biosimilar market entry.

For six years, since the passage of the historic Biologics Price Competition & Innovation Act (BPCIAct) which first set the stage for biosimilars in 2010, the key figures shaping the evolving US biosimilars landscape have convened at our annual conference to formulate solutions to the challenges facing the industry. Don’t be left behind- arm yourself with an immediate action plan to prepare for the hard-fought battle to protect or increase market share which is sure to come.

Join us for an up-to-the-moment treatise on the significant regulatory and IP developments affecting US biosimilars. Event highlights include:

• Keynote address by Julia Pike, Head Global IP Litigation at Sandoz
• Comparing and contrasting the US and EU biosimilars experience to date to prepare and coordinate a global strategy based on insights from experts at AbbVie, Boehringer, IPM Biotech, PAREXEL, and more
• Meeting USFDA’s standards for biosimilarity and the heightened standard for interchangeability
• Evaluating the risk and commercial opportunity within the burgeoning US biosimilars market
• Obtaining adequate patent protection in the US in light of major changes to subject matter patentability and new USPTO patent office procedures

PLUS! A full day workshop designed to bring EU attorneys up to speed on the statute and the relevant governing bodies: Biosimilars 101: Essential Training for EU Pharmaceutical Lawyers on the Relevant US Regulatory and Legal Landscape

We hope you will join us in Munich and be part of the community of leaders shaping the law in the years to come.

Very truly yours,

Nicole M. Cutrufello-Turner, J.D.

Legal Analyst and Senior Conference Director

Who You Will Meet

• Patent Attorneys (in-house and law firm), Regulatory Counsel, Business Executives, Competition Lawyers, and Policy Analysts for:
  ○ Innovator pharmaceutical and biotechnology companies
  ○ Generic and biosimilar pharmaceutical and biotechnology companies
Biosimilars 101: Essential Training for EU Pharmaceutical Lawyers on the Relevant US Regulatory and Legal Landscape
This immersive session is designed for EU biopharma attorneys who need to know more about the US biosimilars statute and gain clarity on the relevant governing bodies now that companies are moving full speed ahead with the first US biosimilars applications. Attendees will walk away with an up-to-the-moment treatise on the significant regulatory and IP developments affecting US biosimilars, setting the stage for the rest of the conference.

9:00 Co-Chairs’ Opening Remarks
Kurt R. Kars
Director
Hyman, Phelps & McNamara, P.C. (Washington, DC)
Kevin E. Noonan, Ph.D.
Partner
McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

Diving Into the Science of Biologics and Biosimilars: What Counsel Needs to Know to Formulate a Regulatory and Patent Strategy
Victoria L. Brewster, Ph.D.
Partner (Patent Attorney)
FisherBroyles, LLP (Palo Alto, CA)

Bernard A. Brown II, Ph.D.
Patent Attorney
Womble Carlyle Sandridge & Rice, LLP (Winston-Salem, NC)

Fangli Chen, Ph.D., J.D.
Partner
Choate Hall & Stewart LLP (Boston, MA)

Denise M. Kettelberger, PhD, JD
Counsel
Sunstein Kann Murphy & Timbers LLP (Boston, MA)

Dr. Arno Kromminga
CEO
IPM Biotech (Hamburg, Germany)

Diane P. Tso, Ph.D., J.D.
Of Counsel
Lerner David Littenberg Krumholz & Mentlik LLP (Westfield, NJ)

- Overview of the key differences between drugs and biologics
  - Living organisms versus chemically synthesized molecules
  - Types of biologics which may be ripe for a biosimilar including monoclonal antibodies, therapeutic proteins, and vaccines
- Appreciating the impact of changes in structure, formulation, or impurities on biologic products and understanding how this affects immunogenicity
  - Structure / Function relationships
  - Manufacturing issues, drift, and product evolution
  - Drug delivery mechanisms
  - Breaks in cold handling chain
  - Improper patient storage and handling

10:30 Understanding the Structure of the USFDA and Its Role in Approving and Regulating Biosimilars
Cecil Nick
Vice President (Technical)
PAREXEL International (Uxbridge, United Kingdom)

Areta L. Kupchyk
Partner
Nixon Peabody LLP (Washington, DC)

- Identifying key USFDA centers and comprehending the role of Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) in the biosimilars process
- Examining the jurisdiction of the USFDA to create the regulatory framework for an abbreviated approval process for biologic products under Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics Price Competition and Innovation Act of 2009 (BPCIA)
  - Detailing the policy objectives behind the passage of the BPCIA as part of healthcare reform: going behind the scenes into the history and political dynamics behind the legislation and the failed challenge of healthcare reform at the US Supreme Court
- Understanding how user fee funding under the Biosimilar User Fee Act (BsUFA) impacts biosimilar applications
  - Biological project development (BPD) fees
  - Timeframes for review
- Working with the USFDA: industry comments and formal and informal dispute resolution mechanisms
  - Status and recap of key citizen’s petitions received to date: Abbott, Amgen, GPhA, Janssen and more
- Exploring the implications of the new “Purple Book” listing biologics that may serve as reference products for biosimilars and interchangeables

11:15 Morning Coffee Break

11:30 Delving into the Mechanics of the USFDA Biosimilars Approval Process and Section 351(k) Applications Under the Pathway
James N. Caaban
Partner and Chair, FDA Practice Group
Wiley Rein LLP (Washington, DC)

Robert M. Gould, Ph.D.
Partner
Husch Blackwell LLP (Chicago, IL)

- Going over important definitions in the Act including “biological” and “biosimilars” and “reference product”
- Exploring key provisions in the Act
  - Criteria for biosimilarity and interchangeability
  - Clinical trials and safety studies
  - Exclusivity provisions
  - Patent litigation and exchange provisions: Understanding the major differences between small molecule Hatch-Waxman litigation and biosimilars litigation as outlined in the statute

- 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
- Determining what may constitute a “biobetter” and choosing whether to seek pure “biosimilarity” or an improved “biobetters” product or both

- Improper patient storage and handling
- Breaks in cold handling chain
- Manufacturing issues, drift, and product evolution
- Drug delivery mechanisms
- Types of biologics which may be ripe for a biosimilar including monoclonal antibodies, therapeutic proteins, and vaccines
- Living organisms versus chemically synthesized molecules
- Structure / Function relationships
- Overview of the key differences between drugs and biologics
• Recapping the statements and guidance issued by USFDA post-BPCIA: what are the open questions?
  - February 2012 three-part guidance pertaining to scientific and quality considerations in demonstrating biosimilarity to a reference product
  - March 2013 guidance regarding closed-door meetings and biosimilars user fees
  - May 2014 Guidance on Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product
  - August 2014 Guidance on Reference Product Exclusivity for Biological Products
• Submitting an application under 351(k): what must be included in its content?
• Examining the specific provisions for patent resolution under the statute
  - Certification procedures
  - Procedures for patent identification
  - Mechanisms of negotiation and engaging in good faith negotiations
  - Settlement processes
• Calculating data and patent exclusivities under the Act
• Comparing and contrasting the biosimilars pathway under the statute to 505(b)(2) and BLA pathways
  - Breakdown of relevant considerations with each route including timing, costs, IP litigation considerations, and exclusivities

Afternoon Coffee Break

Obtaining Adequate Patent Protection in the US: Factoring Key Cases into Your Biosimilars Patent Strategy

Kathryn Doyle, Ph.D.
Partner
Saul Ewing LLP (Philadelphia, PA)

Steve Lendaris
Partner
Baker Botts LLP (New York, NY)

John J. Molenda, Ph.D.
Partner
Steptoe & Johnson LLP (New York, NY)

Cynthia Soumoff, PhD
Partner
Meagher Emanuel Laks Goldberg & Liao, LLP (Princeton, NJ)

• Operating in an “anti-patent climate”: Establishing realistic expectations for the scope of patent protection in view of § 101 patentability developments
  - Association for Molecular Pathology v. Myriad Genetics
  - Mayo v. Prometheus
  - Alice Corp. v. Cls Bank International
  - Update on USPTO draft guidance on § 101 patentability
• Analyzing how current US IP case law will shape claiming and litigating biosimilars
  - 112 issues and patent claim indefiniteness post-Biovig Instruments, Inc. v. Nautilus, Inc. and Abbvie v. Janssen
  - Momenta v. Amphastar and the safe harbor
  - Understanding the evolution of double patenting type obviousness
  - Portfolio management in light of the Gilead Sciences Inc. v. Natco Pharma Ltd. and Novartis v. Lee
  - Claim construction post Teva Pharmaceuticals USA Inc. v. Sandoz Inc.


Emily A. Alexander
Director, External Affairs, Biologics Strategic Development
AbbVie, Inc. (North Chicago, IL)

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

• Examining the role and responsibility of the US Federal Trade Commission (FTC) in protecting competition in the biosimilars space

1:30  Networking Lunch

1:30 Mastering the Essentials of New USPTO Post-Grant Proceedings For Effective Use in the Biosimilars Space

Lisa B. Pensabene
Partner and Head of Life Sciences Litigation
O’Melveny & Myers LLP (New York, NY)

John T. Callahan
Partner
Siegrued Mion PLLC (Washington, DC)

Kevin E. Noonan, Ph.D.
Partner
McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

Gina Shishima, Ph.D.
Partner and Head of IP Transactions and Patent Prosecution
Norton Rose Fulbright (Austin, TX)

• An overview of USPTO Post-Grant Procedures: considerations including discovery, timing, standards for claim construction, and cost
  - Inter Partes Review (IPR)
  - Post Grant Review (PGR)
  - Third Party Pre-Issuance Submissions
  - Covered Business Method Patent Review
  - Ex-Parte Re-Examination
  - Supplemental Proceedings
  - Patent Reissue
  - Derivation Proceedings
• Understanding how these proceedings affect patent practice before the USPTO while also serving as a parallel or alternate administrative avenue to District Court litigation
• Examining how life sciences patents are particularly vulnerable to attack in the USPTO on challenges based on subject matter, written description, lack of enablement and more

2:30

2:45
5:00 Preconference Boot Camp Adjourns

Main Conference: Tuesday, April 21, 2015

8:00 Registration and Continental Breakfast

8:30 Co-Chairs’ Opening Remarks

8:45 Minimizing the Uncertainty Surrounding the Pathway: Insights Into USFDA’s Current Initiatives Regarding the First Wave of Biosimilars Applications

James N. Czaban
Partner
Wiley Rein LLP (Washington, DC)

Christina M. Markus
Partner
King & Spalding LLP (Washington, DC)

- Understanding the USFDA’s “totality of the evidence” and case-by-case approach to biosimilar approval
  - Update on the closed-door meetings between manufacturers and USFDA
- Meeting USFDA’s standards for biosimilarity and the heightened standard for interchangeability: how are companies moving forward in light of lingering open questions from draft guidance?
- Demonstrating biosimilarity: What exactly will a company need to show?
  - Putting together a step-wise approach
  - Showing safety and efficacy through clinical trials: Looking to innovators’ trial design and endpoints
  - Extrapolating data: what will be acceptable? (i.e. between populations within indications? Across unrelated indications?)
  - To what extent will bridging studies of ex-US data be acceptable?
  - What are companies doing in the absence of final guidance?
- Anticipating when final USFDA guidance regarding biosimilars will be issued in light of the first applications being public
- Substituting the biosimilar at the pharmacy level: what will it take to make interchangeability a reality and how can manufacturers maintain this over time?

9:45 Evaluating the Risk and Commercial Opportunity in the Emerging U.S. Biosimilars Landscape

Joseph P. Fuhr Jr., Ph.D.
Professor, Economics
Widener University (Chester, PA)

- Navigating the burgeoning US biosimilars market
  - Who are the key players in the US market?
  - Identifying biosimilar product submissions to date
- Understanding the blurred lines between traditional innovators and generics
- Determining the potential value of U.S. biosimilars revenue
- How much money is there in the current U.S. biologics market?
- Examining the drivers shaping the biosimilars market
- Factoring in the “patent cliff” and shifting industry dynamics which may make biosimilars even more attractive
- Discussing which biologics are particularly vulnerable to biosimilars competition going forward

- Cost-benefit analysis: Determining the potential value of biosimilars revenue based on relevant IP, regulatory, and commercial factors
  - Estimated development costs and production capital needed
  - Pricing considerations for follow-on products: how similarly will the biosimilar need to be priced to the branded product?
  - Estimating market penetration for biosimilar products
  - Reimbursement and insurance issues
- Exploring the unique alliances forming in the market: who has the manufacturing capability and capital to produce and commercialize a biosimilar?
  - Update on the key collaborations to date: which have fallen through and which are still going?

10:45 Morning Coffee Break Sponsored By:

11:00 In-House Keynote Address

Julia Pike
Head Global IP Litigation
Sandoz (Munich, Germany)

Timing is Everything: A Cheat Sheet for Managing the Logistics of the BPCIA Exchange Process

Shatrada E. Dewaneetty
Senior Patent Counsel
Boehringer Ingelheim (Ingelheim, Germany)

Irena Royzman, J.D., Ph.D.
Partner
Patterson Belknap Webb & Tyler LLP (New York, NY)

Brian V. Slater
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

Donald R. Ware
Partner
Foley Hoag LLP (Boston, MA)

- Understanding how BPCIA timelines play out in practice
  - Preparing for “early” and “late” phase litigation: making the decision from an Applicant’s standpoint whether to engage or defer litigation to the later phase
  - “Designing around” the timelines
  - Vetting your patents to determine which ones to assert in the first wave versus the second
- Having contingency in plans now in order to move swiftly once the subsection (k) filing triggers the patent dance and its strict timeframes
  - Pre-litigation posturing: managing the logistics of the IP exchange process, given the extreme deadlines
  - Using the new Purple Book to creating your “slates” of suggested patents or deciding which patents to challenge
- Evaluating the patents in your portfolio which may be the subject of litigation and doing the required due diligence now
- Communicating with the relevant inventors and preparing them for potential litigation
- Deciding whether to provide a (k) application and, if so, determining what other information to provide
- Preparing in advance the initial patent list and who can review the (k) application
- Preparing in advance non-infringement and invalidity contentions
- Understanding the potential consequences of an Reference Product Sponsor (RPS) not responding with a detailed, claim-by-claim response
- Mandatory negotiations: strategic considerations for deciding whether to limit the number of patents RPS can assert in the "early phase" litigation
- Understanding the importance of Patent Term Extension in a biosimilars scenario
- Minimizing confidentiality issues inherent in the statutory private list exchange process

2:00 Afternoon Coffee Break Sponsored By: Steptoe & Johnson LLP

2:15 Biosimilars Litigation Spotlight: Immediate Action Plans for Innovators and Biosimilars to Prepare For the Battles to Come

Stephen R. Auten
Partner
Taft Stettinius & Hollister LLP (Chicago, IL)

Leora Ben-Ami, P.C.
Partner
Kirkland & Ellis LLP (New York, NY)

Elaine Herrmann Blais
Partner
Goodwin Procter LLP (Boston, MA)

Morgan Chu
Partner
Irrell & Manella LLP (Los Angeles, CA)

- Reviewing the BPCIA cases filed to date and analyzing the substantive arguments in the first cases
  - Sandoz v. Amgen
  - Celltrion v. Janssen
- Bringing declaratory judgment actions to invalidate patents pre-suit post-District Court decision in Sandoz: will companies attempt to make this argument in other jurisdictions?
- Understanding what this means to the timing of patent filings: making the decision to file pre-suit, waiting out the lengthy legal process, or launching without the benefit of having discovery of the other party's patents and legal positions
- Developing patent certainty: factoring the decisions in the BPCIA case into BLA versus biosimilar application analysis and into forum choice between District Courts, USPTO, and the ITC?

3:15 Incorporating Inter-Partes Review and New USPTO Procedures Into Branded and Biosimilar Litigation Strategies

Sandra A. Frantzen
Shareholder
McAndrews, Held & Malloy, Ltd. (Chicago, IL)

Thomas J. FilarSKI
Partner
Steptoe & Johnson LLP (Chicago, IL)

Benjamin C. Hsing
Partner
Kaye Scholer LLP (New York, NY)

Patrice P. Jean, Ph.D.
Partner
Kenyon & Kenyon LLP (New York, NY)

- Integrating the monumental changes under the AIA including inter partes review and post-grant review into your biosimilars prosecution and litigation strategies
  - Inter-partes review (IPR)
  - Post-grant review (PGR)
  - Reexamination
  - Supplemental examinations
  - Derivation proceedings
- Anticipating how the complex patent resolution provisions in the BPCIA will interplay with the administrative patent validity proceedings at the USPTO including:
  - Adjudicating patent validity at the USPTO level
    - Factoring in collateral estoppel considerations
    - Parallel litigation in two forums: Creating a record in the patent office and managing multiple concurrent proceedings
    - Exploring judicial recourse from USPTO decisions: how much deference must a Court accord to the patent office?
- Specific considerations for brand-versus-brand and generic-versus-generic
- Updating your freedom to operate analysis to account for new AIA standards

4:15 Afternoon Coffee Break

4:30 Open Floor Session: Lessons Learned so Far: Comparing and Contrasting the US and EU Biosimilars Experience

Lorna Brazell
Partner
Osborne Clarke (London, United Kingdom)

Karine Crepin, PhD, EPA
AVP, Global Head of Biologics Patents
Sanofi (Paris, France)

Fiona Stevens
Partner
Gill Jennings Every LLP (London, United Kingdom)

- Highlighting the key similarities and differences between the US and EU frameworks
- Preparing your global biosimilars portfolio to coordinate regulatory and litigation strategies and positions in a global setting
- How might the FDA follow the EMA's lead:
  - Clinical and comparability studies
  - Naming
  - Pricing
  - Interchangeability and substitution
- Studying approvals to date:
  - What have the actual costs been and what is the market uptake?
  - Product specific tips: adverse events or safety signals to date from the biosimilars in EU market which American companies should prepare to address
- Update on key EU biosimilars patent litigation battles: what are the strong arguments and defenses being used?

5:15 Conference Concludes
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