American Conference Institute’s 2nd Annual Conference on

BIOSIMILARS

The Definitive Forum on the Legal, Regulatory, and Commercial Realities of Generic Biologics

June 7-8, 2011 • The Millennium UN Plaza • New York, NY

Come to the definitive forum where all the key players in the biosimilar market – decision-makers at branded and generic pharmaceutical and biotech companies, policy experts from major industry associations, the scientists and economists who are helping to shape the pathway, and leading regulatory and patent lawyers – unite to provide you with the tools necessary to position yourself strategically in anticipation of generic biologic entry including:

• Understanding the FDA’s current position on the implementation of a biosimilar pathway and strategically positioning your company to protect or increase market share
• Determining what level of clinical data biosimilar applicants must provide to prove safety and efficacy
• Evaluating the impact that the 12-year exclusivity period will have on competition and research and development
• Assessing the financial viability of biosimilars in light of potential regulatory hurdles and forecasting potential profit margins
• Developing proactive strategies and plans in preparation for the eventuality of biosimilar patent disputes

Pre-conference science primer on Biologicals Science 101: Understanding and Deconstructing the Complicated Scientific Principles Behind Biosimilars
Post-conference master class, an In-Depth Breakdown of the Biosimilar Framework in the EU

Benefit from an exceptional faculty of industry experts including:
Abbott Biotherapeutics Corporation
Barnett Institute of Chemical and Biological Analysis
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Biotechnology Industry Organization (BIO)
Biovail Laboratories International SRL
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Dr. Reddy’s Laboratories
Duke University, The Fuqua School of Business
Eli Lilly and Company
Emergent BioSolutions
Genzyme Corporation
Global Healthy Living Foundation
Merck BioVentures
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Teva North America
And many more…

Distinguished Co-Chairs:
Amy E. Hamilton
Vice-President – Deputy General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

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

“One of the best CLEs I’ve been to in 10 years”
Maryann Wiskerchen, Counsel, Eli Lilly & Co.

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Vice-President – Deputy General Patent Counsel
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Donald R. Ware
Partner, Foley Hoag LLP (Boston, MA)
Attending the one event where the industry leaders driving the business of biosimilars unite to set the standards which will shape an evolving legal and regulatory landscape

The Biologics Price Competition & Innovation Act (BPCIA) was passed in March of 2010 and made the long-anticipated pathway to generic biologic products a reality at last. However, despite the passage of this historic legislation, the FDA has yet to implement regulations to guide branded and generic companies in structuring a biologics regime. At ACI’s second-annual Biosimilars conference, the key figures who are shaping the evolving biosimilar landscape—leading policy makers, in-house representatives from branded and generic biotechnology and pharmaceutical companies, and top-tier litigators and patent prosecutors—will convene to formulate solutions to the challenging questions left standing in the wake of the historic BPCIA legislation:

- Meeting the heightened standard of interchangeability and proving or disproving similarity
- Delineating the scope of the exclusivity provision and analyzing the potential impact of the statutory 12-year period on research, innovation and consumer access to drugs
- Analyzing the complex patent resolution mechanisms outlined in the statute and proactively preparing for the intricate exchange process
- Ascertaining the volume and level of safety data that will be required to prove patient safety and efficacy to facilitate approval
- Determining the financial viability of biosimilars and exploring alternative pathways to approval including biobetters

The major players are preparing for the inevitable—the litigation and the attacks on biosimilar IP that are sure to come

With an estimated $100 billion in potential biologics sales at stake annually and a wave of patent expirations starting in 2014, there will be a hard-fought battle to protect and increase market share. Whether you are on the branded or generic side, you cannot afford to miss this opportunity to benchmark your tactics and strategies against the industry leaders who will be the first to traverse the pathway. Devise an immediate action plan for your biosimilar prosecution and litigation strategies in light of the barriers to entry, research and development costs, and regulatory hurdles, which are balanced against an enormous potential for increased profit margins.

Get the complete picture: The science, the law, the regulations and the international framework

Come away with a clear understanding of the scientific aspects of biosimilars at our pre-conference primer on Biologics Science 101: Understanding and Deconstructing the Complicated Scientific Principles Behind Biosimilars. At this in-depth session, leading scientists and academics will translate the technical and scientific complexities behind generic biologics into usable data to factor and incorporate into your business plan.

Finally, complement your whole conference experience with our Master Class which will provide an In-Depth Breakdown of the Biosimilar Framework in the EU at which leading practitioners on the ground will dig into the regulatory and commercial specifics of the already-launched EU biosimilar framework. Dive into the nitty-gritty details about launching biosimilars in the EU as well as best practices to implement based on the success of generic launches there.

With all that is at stake, do not miss this opportunity to remain at the forefront of this pivotal growth opportunity into the long-awaited biosimilar market. Register today by calling 888-224-2480, fax your form to 877-927-1563, or online at www.AmericanConference.com/FOB.

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Pre-Conference Primer: Monday, June 6, 2011
2:00 pm – 5:00 pm (1:30 pm Registration)

Biologics Science 101: Understanding and Deconstructing the Complex Scientific Principles Behind Biosimilars

Graham Jones, Ph.D., D.Sc.
Professor and Chair
Barnett Institute of Chemical and Biological Analysis
Northeastern University (Boston, MA)

Denise M. Kettelberger, Ph.D., J.D.
Special Counsel
Faegre & Benson LLP (Minneapolis, MN)

Gillian R. Woollett, M.A., D.Phil.
Chief Scientist
Engel & Novitt, LLP (Washington, DC)

Understanding the minutiae and complicated science of biosimilars is paramount in formulating a biosimilar business strategy. Unlike small molecule drugs, the complex nature of biologics (most are produced in living organisms) makes it difficult to produce a highly similar copy of a reference biological product. Innovator products have already demonstrated that even minor changes in biologic manufacturing processes can result in major changes in efficacy or immunogenicity. In this in-depth and interactive primer, scientists on the front lines of research and development and thought-leaders who are guiding clients and the FDA on the relevant scientific considerations will maximize your understanding of the science, putting you in the best position to assess actual costs of biosimilar research and development and to integrate this assessment into appropriate life cycle management considerations for all biologics. Through a greater understanding of regulatory options, the session will also allow better evaluation of the value of intellectual property in terms of both regulatory exclusivity and patents.

- FDA implementation of a pathway for biosimilars and interchangeable biosimilars
- Challenges with specific product manufacturing processes
- Switching studies - Clinical trial design and immunogenicity concerns
- Understanding structure / function relationships
- Biosimilar monoclonal antibodies- technical challenges in process development
- Reference product selection - key differentiating principles for similarity and comparability
- Relationships between PHS Act licensed products, and biologic drugs approved under FD&C Act – future changes
- Why the Hatch Waxman small molecule model will work for biologics and why it won’t

Day 1: Tuesday, June 7, 2011

7:30 Registration and Continental Breakfast

8:15 Co-Chairs Opening Remarks

Amy E. Hamilton
Vice-President- Deputy General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

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

8:30 Update on Current FDA Position and Initiatives Regarding Biosimilars

Paul T. Kim
Partner
Foley Hoag LLP (Washington, DC)

- One year post-approval for the abbreviated biosimilar pathway: Where are we now?
- Forecasting the future of biosimilars: what are the expected timelines for implementation?
- Uncovering specific issues and challenges presented by key stakeholders at the November 2010 FDA hearings based on published comments

9:00 Predicting, Preparing and Positioning for the FDA’s Implementation of the Biosimilar Pathway

James Bauersmith
Senior Counsel, Legal Affairs
Teva North America (North Wales, PA)

Kay Holcombe
Senior Health Policy Advisor
Genzyme Corporation (Washington, DC)

David E. Korn
Senior Assistant General Counsel
PhRMA (Washington, DC)

Gregory J. Glover, M.D., J.D.
Principal
Pharmaceutical Law Group PC (Washington, DC)

In this session, leading experts will provide insight and discuss strategies for implementing a biosimilar pathway in accordance with FDA guidance. Topics to be discussed include:

- Surveying the battle field: how are the key players lining up?
- What should you be doing now to make sure you are best situated to meet potential deadlines?
- Action plans for key provisions of the Biologics Price Competition and Innovation Act of 2009:
  - Biosimilarity
  - Interchangeability
  - Clinical data requirements
  - Patent resolution mechanisms
  - Naming considerations
  - Exclusivity (data, market and pediatric)
- Understanding the legislative intent behind the statute to prepare for any challenges to FDA’s rulemaking
- Exploring potential practical challenges to biosimilars under healthcare reform

“Excellent program – informative and thought-provoking”
Mark Bowditch, Patent Attorney, Sandoz Inc.

“I thought all the speakers did an excellent job in terms of content and delivery”
Gregory York, Associate, Pearne & Gordon LLP
9:45 Scrutinizing the Costs and Complexities Behind Biosimilar Research and Development

**Steve Auten**
Vice-President, Legal- Intellectual Property
Sandoz (Princeton, NJ)

**Elizabeth Holloway**
Business Analyst
Biogen Idec (New York, NY)

**Chris Slavinsky**
Assistant General Counsel, Established Products Business Unit
Pfizer, Inc. (New York, NY)

- What does the current biologic market look like?
- Identifying “blockbuster” biologics
- What will the commercial impact of generics be?
  - Effect on stock prices
- Determining which biologics are particularly vulnerable to follow-on competition
- Blurring the lines between traditional innovators and generics
- Alternative paths and new alliances created by a 12-year exclusivity period
- Shifting resource allocation between innovation versus de-risk portfolios
- Assessing barriers to entry for competitive products: does it make sense to use the abbreviated pathway?
- Realistically forecasting profitability when factoring in regulatory hurdles and production costs
- Factoring in the high costs of manufacturing a biologic product
- Exploring incentives for both innovators and follow-on companies to research and develop new treatments

10:45 Morning Coffee Break

11:00 No Two Biologics are Alike: Defining Biosimilarity and Meeting the Heightened Standard of Interchangeability Under the Statute

**Graham Jones, Ph.D., D.Sc.**
Professor and Chair
Barnett Institute of Chemical and Biological Analysis
Northeastern University (Boston, MA)

**Rochelle K. Seide, Ph.D., J.D.**
Former Vice President, Intellectual Property
Biovail Laboratories International SRL
(Barbados, West Indies)

**Madison C. Jellins**
Partner
Alston & Bird LLP (Palo Alto, CA)

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

- Outlining the parameters of similarity in the context of large complex biological compounds
- What does it mean to be “highly similar”?
- Grounding the regulations governing biosimilars in science: An overview of the mechanics of biosimilars

12:15 Networking Luncheon

1:30 Debating the Practical Implications of a 12 Year Exclusivity Period: Striking a Balance Between Innovator and Biosimilar Interests

**Sandra J.P. Dennis**
Deputy General Counsel for Healthcare Biotechnology Industry Organization (BIO)
(Washington, DC)

**Henry G. Grabowski, Ph.D.**
Professor Emeritus
Duke University, The Fuqua School of Business
(Durham, NC)

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

- The evolution of the 12-year data exclusivity period
- The difference between data and market exclusivity
- What changes in biological structure will allow for an additional exclusivity period?
- The impact of a 12-year data exclusivity period: what are the implications to both generic and branded companies if it is lowered?
- Does data exclusivity for biologics in the US have any meaning that one can use to predict competition and generic entry?

2:45 Afternoon Refreshment Break

3:00 Branding and Promotional Considerations for Biosimilars

**Gillian M. Cannon**
Vice President for Product Development
Merck Bioventures (Rahway, NJ)

- Commercialization challenges
- Varying nomenclature
  - How distinct does the follow-on product name have to be from the original?
  - The benefits and drawbacks of a unique nonproprietary name to distinguish biosimilars from reference products
- Creating a marketing plan in light of biosimilars
- Meeting the challenge of the broad capabilities required
Day 2: Wednesday, June 8, 2011

7:45  Registration and Continental Breakfast

8:15  Co-Chairs Opening Remarks

Amy E. Hamilton  
Vice-President- Deputy General Patent Counsel  
Eli Lilly and Company (Indianapolis, IN)

Donald R. Ware  
Partner  
Foley Hoag LLP (Boston, MA)  
Preparing for the Reality of Biosimilar Patent Litigation

8:30  An Overview of the Statutory Dispute Resolution Mechanisms: Steering Clear of Any Potential Gaps in the Litigation

Hans Sauer, Ph.D., J.D.  
Associate General Counsel for Intellectual Property  
Biotechnology Industry Association (Washington, DC)

Jessica Wolff  
Partner  
Cooley LLP (San Diego, CA)

Ha Kung Wong  
Partner  
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

• Exploring the mechanisms in place under Title VII, Subtitle A of the BPCI Act  
  - Patent exchange  
  - Good faith negotiations  
  - Remedies and injunctions  
  - Declaratory judgment actions  
  - Damages  
• Implications of dropping the Orange Book  
• Assessing the degree to which the Hatch-Waxman model applies to follow-on biologics  
  - Contrasting the Paragraph IV Litigation with anticipated FOB litigation  
• Meeting the burden of proving infringement  
• Remedies with respect to infringement, including when preliminary and permanent injunctions are available

9:45  Morning Coffee Break

4:00  Learning from the Global Development of Biosimilars: Enforcement and Risk Management Strategies to Protect your Biologic on the International Stage

Naomi Pearce (Invited)  
IP Director and Counsel  
Hospira, Inc. (Australia)

Adrienne M. Blanchard  
Partner  
Gowling Lafleur Henderson LLP (Ontario, Canada)

Candi Soames, Ph.D.  
Partner  

Michael J. Wise  
Partner / Chair, China Intellectual Property Practice  
Perkins Coie LLP (Los Angeles, CA)

• Surveying the European patent landscape: Understanding how new case law and evolving rules will affect claiming and litigation strategies  
• Filing claims of sufficient scope in light of new rules on divisional applications  
• Exploring opportunities for growth into global markets: infringement risk assessment and claiming strategies for emerging markets including China and India  
• Understanding Subsequent Entry Biologics (SEBs) in Canada  
• Accounting for generic biologics being treated the same as generic small molecule drugs  
• Price controls for follow-on biologics  
• How cost-effective have launches of generic biologics been around the world? Case studies and comparisons from actual product launches  
• To what extent is there a possibility of harmonization between global regulations of generic biologics?  
• How might the US follow established laws governing biosimilars in the EU and Canada?

5:15  Conference Adjourns to Day 2

WHO YOU WILL MEET:

- Patent Attorneys (in-house and law firm), Regulatory Counsel, Business Executives, and Policy Analysts for:  
  - Brand name pharmaceutical companies  
  - Generic pharmaceutical companies

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12:30 Networking Luncheon

1:30 Ascertaining the Type and Volume of Clinical Data Necessary to Establish Biosimilarity

**Dr. Michael Bui, DDS, MPH, JD**
Associate Director, Global Regulatory Strategy, Oncology Bayer Healthcare Pharmaceuticals (Montville, NJ)

**Seth D. Ginsberg**
President
Global Healthy Living Foundation
(Upper Nyack, New York)

**Magdalena Leszczyniecka, Ph.D., M.B.A.**
Co-Founder and Chief Executive Officer
STC Biologics, Inc. (Cambridge, MA)

**Anshuman Patwaharan, Ph.D., MBA**
Senior Director, Portfolio Strategy and Licensing
Dr. Reddy’s Laboratories, Ltd. (Bridgewater, NJ)

**Moderator:**

**Brian J. Malkin**
Partner
Frommer Lawrence & Haug LLP (New York, NY)

- What will FDA require in terms of clinical testing?
- Meeting the standard of “no clinically meaningful differences”
- Striking a balance between requiring larger and more sophisticated trials and facilitating market entry for biogenerics
- Understanding the patient perspective in the biosimilar conversation
  - Biologic and biosimilar safety and efficacy
  - Pharmacovigilance: collecting, monitoring, researching, assessing and evaluating adverse events
  - Cost to the patient
  - Therapeutic substitution issues
  - Barriers to care
- What level of support will FDA require to get approval?
- Extrapolating data obtained in clinical trials for a reference product to support biosimilar applications
- What indications can you use for the biosimilar?
  - Head-to-head trials
- Relying on data provided by ex-U.S. companies for comparator products
- Evaluating the potential for citizens’ suits based on safety and efficacy when evaluating safety and efficacy for complex and multifaceted molecules
- Contrasting clinical and animal study requirements in connection with a 351(k) application

2:45 Afternoon Refreshment Break

3:00 Structuring a Patent Portfolio Strategy to Protect IP in Light of FOB Legislation

**Amy E. Hamilton**
Vice-President- Deputy General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

**Janis K. Fraser, Ph.D.**
Principal
Fish & Richardson (Boston, MA)

- Deciding which patents to litigate in the first phases versus the second phase
- Where the parameters of the safe harbor lie post-Merck v. Integra and what is applicable to biosimilars
- Deciding where to litigate
- Strategic discovery considerations: what you need and how to get it quickly
- Managing the litigation and working with multiple co-plaintiffs
- Special strategic considerations for companies following both branded and follow-on paths
Raymond R. Mandra  
Chair, Biotechnology Practice Group  
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

K. Shannon Mrksich, Ph.D.  
Co-Chair, Biotechnology Practice Group  
Brinks Hofer Gilson & Lione (Chicago, IL)

- Update on current case law affecting your portfolio  
- Written description and enablement requirements in light of *Ariad* and *Centocor*  
- Method claims and the viability of patenting genes after *Myriad*  
- Assessing your existing portfolio  
- Using your pending applications to claim future biosimilars  
- Considering obviousness type double patenting of copending cases  
- Ensuring a broad scope of patent protection while crafting claims that cover products and processes  
- Anticipating attacks premised on written description and enablement  
- Protecting against designs-around  
- Claim drafting strategies to ensure maximum patent life for your biologic

4:00  
**Alternative Routes to Market for Biosimilars: Evaluating the Benefits of Using the Abbreviated Pathway**

Thomas F. Gillespie, III  
IP Transactional Counsel  
Emergent BioSolutions (Rockville, MD)

Michelle Lewis  
Senior Counsel  
Bristol-Myers Squibb (Princeton, NJ)

Timothy J. Shea, Jr.  
Director  
Sterne, Kessler, Goldstein & Fox P.L.L.C. (New York, NY)

- Comparison of the biosimilar path versus BLAs (biologic license applications) or 505b2 applications  
- Determining whether research and development resources are best spent on pursuing a biosimilar pathway based on a breakdown of timing, costs and freedom to vary from the original molecule  
- Weighing the benefits of going down a tested trail against the new opportunities inherent in the still-to-be-determined biosimilar route  
- When is a BLA more economically viable?  
- Case studies of market penetration, costs and approval process for existing biologics  
- When to file a BLA  
- Determining the volume of clinical data necessary to file a BLA  
- Determining the validity of “skinny” BLAs and minimum disclosure requirements  
- Evaluating the effectiveness of 505b2 approval through a case study of Omnitrope  
- The possibility of biobetters: how will qualitative superiority be determined for products with the same indications?  
- How will safety and efficacy concerns shape the clinical trials requirements for biobetters?

5:00  
**Conference Adjourns**

In-Depth Breakdown of the Biosimilar Framework in the EU

Maarten Meulenbelt  
Partner  
Howrey LLP (Brussels, BE)

Carla Schoonderbeek  
Partner  
NautaDutilh NV (Amsterdam, NE)

Ulrike Till  
Counsel  
Hogan Lovells LLP (Hamburg, Germany)

- Diving down into the draft guidelines issued by the European Medicines Agency (EMA)  
  - Definition of a biologic and a biosimilar  
  - How does the approval of a biologic compare to a small molecule drug?  
  - Clinical testing requirements to prove safety and efficacy  
  - Exclusivity provisions  
  - Naming conventions and the adoption of an International Nonproprietary Naming System  
- Assessing the vulnerability of monoclonal antibodies in light of the establishment of a pathway by the EMA  
  - Overview on the specific EU guidelines for monoclonal antibodies  
  - Near term competition versus later stage competition  
- Studying approvals to date: what have the actual costs been and what are expected profits?  
  - Understanding the rationale between rejections of human insulin  
- Gaining insights of the competitive landscape in biosimilars: US, EU and emerging markets  
- Leveraging licensing opportunities for biosimilars

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