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FOLLOW-ON BIOLOGICS

The definitive forum on the legal, scientific and commercial realities of biosimilars under Title VII of H.R. 3590

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Interactive Post Conference Workshop:

Applying Patent Term Adjustments and Patent Term Extensions to Biosimilars to Optimize the Biologic Patent Lifecycle

June 23, 2010

Policy makers, in-house representatives from life sciences branded, generic and biotech companies, as well as representatives from key government agencies and industry associations will provide insights and guidance on the new legislation including:

- PREPARE for follow-on patent litigation and UNDERSTAND what mechanisms are and will be in place for resolving patent disputes
- ANALYZE the impact of the 12 year exclusivity period of the financial viability of development of follow-ons
- DEVELOP methods for demonstrating or disproving similarity "in terms of safety, purity and potency of the product"
- DETERMINE what safety data and technical level of support bio applicants will have to provide in order to get approval of follow-ons
- EXAMINE and LEARN from the global development of biosimiliars
- MAXIMIZE the biologic patent lifecycle and PROTECT the value of intellectual property for biologics
- INVESTIGATE alternative approval methods for biosimilars including BLA applications and FD&C 505b2 applications
- EVALUATE the impact of follow-ons on existing and future licensing agreements and strategic alliances

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ATTEND THIS EVENT TO BE AT THE FOREFRONT OF THE CHANGING LEGISLATIVE LANDSCAPE OF HEALTH CARE REFORM AND FOLLOW-ON BIOLOGICS.

On March 23, 2010, President Obama signed H.R. 3590 a/k/a the Health Care Reform bill into law. A pivotal provision of this law allows for an abbreviated pathway for biosimilar biological products. As such and after years of debate, follow-on biologics are now a reality. However, despite this historic passage, many questions remain regarding the implementation and logistics of developing biosimilars.

In response to this, **American Conference Institute,** the leading provider of legal conferences for the life sciences industries and creator of the original and preeminent forums on **Maximizing Patent Life Cycles** and **Paragraph IV Disputes,** has developed this timely event to provide you with the most in-depth analysis of the legal, regulatory, policy and business issues surrounding follow-on biologics.

Based on your feedback, an outstanding faculty of government representatives, in-house counsel and leading legal practitioners will dissect the nuances of the legislation and provide you with insights and guidance on how to prepare for this groundbreaking new legislation. Unlike any other event, this conference will bring you:

- An in-depth view and behind the scenes discussion of the development of follow-on biologics led by industry insiders from the Hill.
- A realistic analysis and assessment of the financial viability of follow-ons including the assessing the barriers to entry, regulatory hurdles and the potential profit margins.
- A clear understanding of the complexity of biosimilarity in addition to methods for proving or disproving interchangeability.
- An exhaustive analysis of the patent resolution mechanisms as well as preemptive strategies for preparing for follow-on litigation.
- Global perspectives on the practical impact of biosimilars in Europe and beyond.
- Industry guidance on proving the safety of follow-on biologics and methods for quickly facilitating the development of safety data for future products

In addition, add value to your experience by attending the interactive Post Conference Workshop: **Applying Patent Term Adjustments and Patent Term Extensions to Biosimilars to Optimize the Biologic Patent Lifecycle.** This hands-on session will provide you with practical advice, as well as tips and techniques for how to extend your patent. The session leader will take you through the intricacies of the major ways of getting an extension on your patent, and provide you with the tools that you need to accomplish this goal in this time of changing rules and regulations.

With all that's at stake, you cannot afford to miss this conference.

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Day 1: Monday, June 21, 2010

7:15 **Registration and Continental Breakfast**

8:15 **Co-Chairs Opening Remarks**

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

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

8:30 **Overview, Status and History of Biosimiliars Legislation in the US: The Inside Story**

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

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

Steven E. Irizarry
Senior Vice President
Capitol Hill Consulting Group
(Washington, DC)

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

The past year has seen a turbulent battle regarding the passing of Health Care Reform. In this session, your expert speakers will not only provide you with an overview of the current legislation, but an in-depth view and behind the scenes discussion of the development and future of follow-on biologics in the US today. Points of discussion include:

- Understanding the political dynamics of the legislation
- What are the provisions regarding biosimilars under Title VII, Subtitle A of the PPACA?
  - What are the likely timelines?
  - Points of agreement and contention in the legislation
- The legislative history behind follow-on biologics and a comparison to how Hatch-Waxman was passed and developed
- What are the first steps to take?
- Implementation issues to be addressed
- The FDA's likely approach
- The interplay with proposed patent reform legislation

9:45 **Practical Implications for the Biosimilars Market under the New Regime**

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

Gregory J. Glover, MD, JD
Principal, Pharmaceutical Law Group, P.C.
(Washington, DC)

Bruce A. Leicher
Senior Vice President and General Counsel
Momenta Pharmaceuticals, Inc.
(Cambridge, MA)

- Legal and commercial characteristics of follow-on biologics market
  - Different roles for patents/patent term restoration
  - Alternative paths and new alliances created by 12-year exclusivity
  - Comparison of incentives for product utilization: generic drugs versus follow-on biologics
  - Greater need for product promotion and branding
- Analyzing the changing business considerations in a biosimilars market
  - The current biologics landscape
    - What biologics have been approved?
    - Identifying the "blockbuster" biologics
    - Determining when biologics are vulnerable to follow-on competition
  - Market differences between brand vs. biosimilars vs. biogenerics
  - Realistically assessing the barriers to entry for follow-on biologics in light of the financial impact of regulatory hurdles and the potential profit margins
  - The commercial impact of generic drugs on the small molecule market and comparisons to the situation for follow-ons
    - Effect on stock prices
    - Gain/loss of market share
  - Demise of the distinction between innovator and follow-on companies
- Assessing the impact of 12-year exclusivity
  - Shifting resources from innovation to de-risk portfolios
  - Effect on life extension strategies for brand biologics
  - Impact on viability
    - Ability to be fast or exclusive
    - Ability to match new manufacturing technology
  - Will 12 years create a window for times launches of biobetters?
- Investment and financing in the world of biosimilars
  - Changes to investments and potential in biotech and pharma in a world of follow-on biologics

- Evaluating and predicting how the entry of follow-ons will affect smaller biotechs and their ability to raise capital
- Impact of follow-on product/company valuations and potential revenue streams
- Assessing the potential profit margins for follow-on biologics, including reimbursement potential

10:45 **Morning Coffee Break**

11:00 **Current FDA Position and Initiatives Regarding Follow-On Biologics**

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

11:30 **Defining Biosimilars: Proving (or Disproving) Interchangeability and Biosimilarity**

Renee M. Kosslak, PhD
General Patent Counsel
Facet Biotech
(Redwood City CA)

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

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

- Understanding how variations in biologics can impact how the molecules are processed in the body
  - Identifying the ingredients and active ingredient(s) in a biologic
- What are the criteria and standards for determining that a biosimilar is "highly similar"?
  - What is similar enough to be considered a biosimilar?
  - What does it take for a biosimilar to be interchangeable?
  - What criteria will the FDA use in order to make the similarity determination?
  - What may be the costs associated with demonstrating similarity?
- Methods for demonstrating similarity "in terms of safety, purity and potency of the product"
- Reviewing examples where changes in manufacturing processes in biologics created difficulty in FDA approvals because of the inability to demonstrate that the products would be identical
  - Applying for similarity determinations for follow-ons
- Debating whether follow-ons approved with an abbreviated pathway are interchangeable or a second generation product with a different commercial market
- Freedom to operate and technical feasibility of maintaining similarity
- Balancing between cost generated by stringent similarity standards with patient access to follow-ons and safety standards

12:30 **Networking Luncheon Hosted By:**

FROMMER LAWRENCE & HAUG LLP

Patent Resolution Processes for Follow-On Biologics Under Title VII, Subtitle A of H.R. 3590

1: 45 **An Overview of Dispute Resolution Mechanisms Under PHS §351**

Barbara A. Fiacco
Partner
Foley Hoag LLP
(Boston, MA)

Hans Sauer, PhD, JD
Associate General Counsel for Intellectual Property
Biotechnology Industry Organization
(Washington, DC)

Thomas J. Filarski
Shareholder, Chair of Chemical Group
Brinks Hofer Gilson & Lione (Chicago, IL)

- Reviewing and the patent resolution processes laid out in the legislation
  - What mechanism will be put in place for resolving patent disputes?
- Examining the specific provisions for patent resolution in Title VII of H.R. 3590
  - Certification procedures
  - Procedures for patent identification
  - Mechanisms of negotiation and engaging in good faith negotiations
  - Settlement processes

2:45 **Afternoon Refreshment Break**

3:00 **Developing Procedures and Strategies in Preparation of Follow-On Litigation**

Mark Bowditch
Patent Attorney, Sandoz, Inc.
(Princeton, NJ)

Pamela D. Politis, PhD., Esq.
Sr. Patent Attorney
Endo Pharmaceuticals Inc.
(Chadds Ford, PA)

Reza Green, Ph.D., J.D.,
Chief Intellectual Property Counsel
Novo Nordisk Inc.
(Princeton, NJ)

Leisa Smith Lundy
Fitzpatrick, Cella, Harper & Scinto
(New York, NY)

- Identifying applicable patents without an orange book
- Minimizing confidentiality breaches with data sharing requirements

- Addressing prosecution bar issue raised by the confidentiality restrictions on in-house counsel who review the FOB application
- Determining whether and when to petition for a preliminary injunction
- Bringing declaratory judgment actions
- Contrasting PIV litigation with anticipated FOB litigation
  - Lessons learned from Hatch-Waxman litigation

4:15 **Maximizing the Biologic Patent Lifecycle and Protecting the Value of IP for Biologics in Light of New Legislation: Written Description, Enablement, the Doctrine of Equivalents and More**

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

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

Raymond R. Mandra
Chair, Biotechnology Practice Group.
Fitzpatrick, Cella, Harper & Scinto
(New York, NY)

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

- Revisiting obviousness for biotech patents
  - The KSR impact – three years later where do we stand?
  - The effect of *In re Kubin*
  - Strategies for strengthening your claims against the obviousness attack
- The written description requirement – How to manage it and why biotechnology patent practitioners should welcome It – Really
  - Incorporating *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* into current patent strategies
  - Defining the proper scope of the written description for biologics
- Defining and demonstrating bioequivalence in biologics
  - Interchangeability and the Doctrine of Equivalents – how does FDA "interchangeability" compare to Warner Jenkins "insubstantial difference"?
  - arguments about bioequivalence raised in patent litigation
- Determining the patentability of diagnostics and gene sequencing in light of *Association for Molecular Pathology and ACLU v. USPTO and Myriad* (S.D.N.Y. 2010)

5:30 **Conference Adjourns to Day 2 Cocktail Reception Hosted by:**

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Day 2: Tuesday, June 22, 2010

8:15 **Registration and Continental Breakfast**

8:45 **Co-Chairs' Opening Remarks**

9:00 **FTC Spotlight: Addressing the Antitrust Concerns Resulting from Follow-On Legislation**

Suzanne Drennon Munck
Counsel for Intellectual Property
Federal Trade Commission
(Washington, DC)

- Analysis of the FTC Report on Emerging Health Care Issues: Follow-on Biologic Drug Competition
- Assessing the impact of follow-on biologics on innovation
- Considering the impact of various market exclusivity periods on competition within the market (5/7/14 years exclusivity)
- Will biologic products qualify for use under state substitution laws?
- Understanding the potential impact of follow-on biologics on pricing
- What are the likely competitive effects of FOB patent resolution processes?

9:45 **Lessons Learned from the Development of Biosimilars on the International Stage**

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

Dr. Fiona Bor
Senior Patent Counsel
Teva Europe Patent Department
(London)

Bert Oosting
Partner, Lovells LLP
(Amsterdam)

- Exploring the EU's stance on follow-on biologics aka biosimilars
- Understanding the EMEA's role in establishing the reference criteria for technical dossiers related to applications for authorization of biosimilars in the EU
  - the EMEA's definition of a biologic and a biosimilar
- A look at the EU approval process for biosimilars through the centralized procedure
  - how does the approval of a biosimilar compare to that of a small molecule generic drug?

- The significance of EMEA's creation of the Biosimilar Medicinal Products Working Party (BMWP)
  - BMWP's role vis-à-vis CHMP's role in the approval and regulation of biosimilars in the EU
- Comparing the EU biosimilar pathway to Title VII of H.R. 3590
  - the EMEA approach to applications for authorization of biosimilars thus far
- Evaluating the business impact of the introduction on biosimilars on the market landscape in Europe
  - What biosimilars have been introduced?
  - What have been the financial ramifications of biosimilars for both branded and generic companies?
- Cases studies on proving biosimilarity in other countries
- Examining the proposed legislation and pathways for follow-on biologics in other countries
  - India, Canada, China
  - How will this impact the market the biosimilars?
  - Comparing and contrasting to the US legislation

11:00 **Morning Coffee Break**

11:15 **Understanding Proposed Clinical Trials Requirements and Overcoming Safety Concerns Associated with Follow-Ons**

Dr. Phoebe Mounts, Esq.
Partner, Morgan, Lewis & Bockius LLP
(Washington, DC)

- What does the legislation require with regards to the submission of safety date for the approval of follow-ons?
  - Testing requirements
  - Naming rules
- What technical level of support will bio applicants have to provide?
  - In vivo and human clinical trials
  - Safety data
  - Purity data
  - Potency
  - Immunogenicity
- Putting internal systems in place now to more quickly facilitate the development of safety data for future products
  - Deciding whether you should commit resources to testing given the state of the legislation
- Applying the REMS requirement to follow-on biologics
- Preparing for the key role of citizen's petitions with follow-ons
  - How much weight will citizen's petitions have?
  - Presenting or defending against questions of safety and efficacy raised in citizen's petitions
  - How will the FDA respond to concerns raised in citizen's petitions and what impact will this have on the approval process?
- Impact of safety standards on product liability litigation

12:30 **Networking Luncheon**

1:45 **Developing Alternative Pathways for Getting Biosimilars on the Market**

Charles Raubicheck
Partner, Frommer Lawrence & Haug LLP
(New York, NY)

- Investigating the process and potential for getting approval of a biologic via a Biologic License Application (BLA)
  - How does the approval process for a biologic differ from that of a drug?
  - Why is it a "license"?
  - What products require BLAs?
  - Analyzing the approval of Neutroval through a BLA application
- Identifying biologics that fall within the purview of Hatch-Waxman
- Analyzing the impact of the 12-year exclusivity period vis-à-vis the probability that BLA usage will be a more viable mode of approval
- Understanding how transitional issues relating to transfer of BLA approved drugs
- Case study of EPO approval
- The Omnitrope story: overcoming the challenges to getting approval through a FD&C 505b2 application

2:45 **Afternoon Refreshment Break**

3:00 **Renegotiating and Reworking Licensing Agreements with Companies and Universities in Anticipation of Follow-On Biologics**

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

- Reevaluating existing licenses to determine the practical and financial impact of follow-ons on the license agreement
- Determining the correct course of action should a university want a patent enforced
- Identifying who has discretion in deciding which products will be launched
- Specific clauses and terms to include in agreements to account for follow-ons
- How do follow-ons impact valuation of products and deals and potential revenue streams?

4:00 **Overcoming Challenges to Marketing, Branding and Promotion of Biosimilars**

Robert A. Dormer
Director, Hyman, Phelps & McNamara, P.C.
(Washington, DC)

- Understanding the different market dynamic for follow-ons
  - No automatic generic substitution provisions

  - Cost of follow-ons as compared to the branded product
- Selecting generic names for follow-ons that maximize branded product as referencing agent without violating trademarks
  - How far in an advertisement can you link the follow-on to the referenced product?
- Creating a marketing campaign that preemptively challenges attacks on safety and efficacy of follow-on products
- Creating a sales team and marketing plan for follow-ons
  - Minimizing potential fraud and abuse violations with the sales force
- Examining the marketing of current "biosimilar" products on the market in the US and abroad
- Accounting for the reaction of physicians in the marketing plan

4:45 **Conference Concludes**

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
- Biopharmaceutical companies
- Biotechnology companies

POST CONFERENCE WORKSHOP

WEDNESDAY, JUNE 23, 2010, 9:00 AM – 12:00 PM

(Registration opens at 8:00 am)

Applying Patent Term Adjustments and Patent Term Extensions to Biosimilars to Optimize the Biologic Patent Lifecycle

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

The effective term of a patent covering a marketed product can be less than the full 20 years if the product is not brought to market by the patent's issue date. This situation is of special interest for biologics, where the regulatory review required for market approval can take many months or even years. The introduction of follow-on biologics has made choosing a mode of patent extension tailored to fit your product a particularly urgent matter.

This hands-on session will provide you with practical advice, as well as tips and techniques for how to extend your patent. The session leader will take you through the intricacies of the major ways of getting an extension on your patent, and provide you with the tools that you need to accomplish this goal in this time of changing rules and regulations. Points of discussion include:

- Extension of patent term under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791
  - 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"
  - Definitions for "drug product" and "regulatory review period"
- The preparation and submission of a patent term restoration application
- Patent term extensions outside the U.S.
- Patent term adjustment due to delays in prosecution before the USPTO and strategies for:
  - Diligence in prosecution by the patent applicant
  - Calculating the adjustment period
- Obtaining patent coverage for biologics through the use of second-generation patents, e.g.,
  - Maintaining patent position for second-generation products
  - Approaches taken by pharmaceutical companies in obtaining second-generation patents enforcement of second-generation patents effect of post-KSR obviousness rulings on their validity

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JUNE 23, 2010

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