The IP Counsel Exchange for Biosimilar Applicants and Innovator Biologic Sponsors

Product Positioning, IP Due Diligence and Enforcement Strategies for Biosimilar and Biobetter Opportunities

January 23-24, 2014 – W Union Square- New York, NY

MAIN CONFERENCE – DAY ONE – THURSDAY, JANUARY 23, 2014

8:30am   Registration & Breakfast

9:15am   Interactive Working Group Sessions

Interactive Working Group A: International IP Developments in the Approval of Biosimilar Products Abroad and What Potential Sponsors and Applicants Can Learn From the European Biosimilars Experience

Andrew Womack*
Director, Science and Regulatory Affairs
Biotechnology Industry Association*

Maria Trallero*
Director, Trade Policy
European Federation of Pharmaceutical Industries and Associations

Bert Oosting
Partner
Hogan Lovells LLP (Amsterdam)

Although the industry continues to await regulatory guidance from the Food and Drug Administration specific to the approval process for biosimilar products here in the U.S., US-based counsel can look to the EU for dispositive guidance on this issue. With regulations first established by the European Medicines Agency (EMA) in 2003 and the subsequent approval of the first biosimilar product in the EU in 2006, the experience of biosimilar applicants and manufacturers in the European market offers a telling story and invaluable lessons learned for companies who will be embarking on this process for the first in the coming months and years, here in the U.S. Particularly with its recent approval of the first two biosimilar antibodies, many companies are looking to Europe to learn from their experience as they contemplate how to best approach the biosimilars market once it opens up here in the U.S.
During this engaging discussion hear from a diverse panel comprised of European counsel with firsthand experience in advising clients on the approval of biosimilar products in Europe, as well as representatives from the European Medicines Agency, Biotechnology Industry Association and the European Federation of Pharmaceutical Industries and Associations as they engage you in an analysis of the key regulatory and IP landscape in the EU and abroad. Please come prepared with your most pressing questions to get the most out of this unique case study session.

*Interactive Working Group B: Dissecting the New Patent Litigation Pathway at the USPTO – Advanced Strategies for Tackling the New Contested Proceedings for Post-Grant Patent and Inter Partes Reviews*

Remy Yucel*
Director
U.S. Patent & Trademark Office

Deborah Sterling, Ph.D.
Director
Sterne, Kessler, Goldstein & Fox P.L.L.C.

During this engaging working group session hear directly from the U.S. Patent and Trademark Office as well as seasoned IP counsel well versed in the nuances of navigating the new post-grant administrative proceedings for post-grant and inter partes review. Offering new and unique benefits for those seeking to protect and proactively defend their patents, litigation at the Patent Trial and Appeal Board (PTAB) has emerged over the past year as an important component of corporate patent litigation strategies. Learn how to effectively utilize these new mechanisms as you gain insider insights for effectively tackling the myriad of challenges presented by the new post-grant patent proceedings as you begin to contemplate what your patent portfolio will look like as a potential biosimilar applicant or innovator biologic sponsor. Learn what steps you may want to take now to shore up one’s IP portfolio as you are provided with an A to Z overview of the pros, cons, business benefits and risks of litigation patents at the PTAB.

10:45am Coffee Break

11:15am Chair’s Opening Remarks

Hans Sauer, PhD, JD
Associate General Counsel for Intellectual Property
Biotechnology Industry Organization

11:30am Patent Caselaw Year in Review
Hans Sauer, PhD, JD  
Deputy General Counsel for Intellectual Property  
Biotechnology Industry Organization

During this session Mr. Sauer will provide a comprehensive update on key caselaw developments under sec 112, examining the impact on patent strategies for companies within the biosimilars space. Learn what impact recent caselaw holdings addressing such critical issues as written description, enablement and obviousness will have on patent strategies going forward particularly within the biosimilar space.

12:15pm  Orange Book Withdrawal

Bruce Pokras  
Senior Patent Counsel  
Pfizer Inc

Ha Kung Wong  
Partner  
Fitzpatrick, Cella, Harper & Scinto

During this session gain proven strategies for conducting effective IP due diligence and patent inventory assessments for biosimilar products in the absence of an established FDA patent listing resource. Topics to be discussed during this panel will include:

✓ Practical tips for updating your data find strategy with an eye towards determining what data you should be evaluating both internally and externally right now
✓ The new patent search do’s and don’ts – insider tips for effectively sweeping the public patent landscape
✓ Effective strategies for upgrading your internal patent portfolio review

1:15pm  Networking Luncheon

2:30pm  So You Think You Can Patent Dance?

Valeta Gregg, PhD, JD  
Vice-President and Associate General Counsel, Intellectual Property
Regeneron Pharmaceuticals, Inc.

Brian V. Slater
Partner
Fitzpatrick, Cella, Harper & Scinto

Now begins the patent dance...hoping to come to an agreement regarding the key patent rights at issue prior to litigation, if not properly prepared for this discussion parties can walk away from the table in no better position than when the conversation first began. During this engaging discussion, hear from senior in-house IP counsel with firsthand experience in engaging in these initial pre-litigation conversations as they provide practical tips and pointers for successfully engaging with opposing counsel with an eye towards limiting the number of patents that are the subject of later ensuing litigation. Topics to be discussed during this session will include:

✓ What to do before meeting with the other side – how to conduct an effective validity analysis of the IP in question
✓ At the table - strategies for best asserting your position on the IP rights in question based on –
  o claim construction requirements
  o written description and enablement standards
  o prior art searches
✓ Tips for narrowing/expanding the rights that are the potential subject of contention – knowing up front what is worth negotiating on vs. what’s not

3:30pm       Afternoon Refreshment Break

4:00pm       Size Matters: Dissecting the Divergent Litigation Pathways of Small vs. Large Molecule Products and What Steps Your Company Should Take Now to Prepare Your Future Litigation Strategy

Shashank Upadhye
Partner
Seyfarth Shaw LLP

Sanya Sukduang
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Understanding the particular challenges the patent litigation landscape around biologic/biobetter will present

✓ Accounting for changes to litigation strategies in light of strict deadlines for patent challenges and new changes to patent law under the AIA

✓ Examining the strategic use of preliminary injunctions in biosimilars litigation

4:45pm  In-House Roundtable Discussion: The Evolving Biosimilar Landscape

Bruce Pokras
Senior Patent Counsel
Pfizer Inc

Rachel L. Schweers, PhD
Attorney
Katten Muchin Rosenman LLP

During this session, be engaged in a conversation between senior IP counsel as they contemplate and discuss the changing generic drug landscape being ushered in by the anticipated approval of biosimilars in the U.S. Topics to be addressed during this panel will include interchangeable exclusions, market exclusivity, alternative monetization strategies for your IP portfolio should your company choose not to enter the biosimilar market and more.

5:30pm  Chair’s Closing Remarks and Adjourn to Day Two

MAIN CONFERENCE – DAY TWO – FRIDAY, JANUARY 24, 2014

9:30am  Chair’s Remarks

9:45am  Addressing the Potential Use of Trade Secrets (Or Not) in Connection with the FDA’s Review of Biosimilar Applications Citing a Reference Product and BLA That Predates the BPCIA

Erika Lietzan
Partner
Covington & Burling LLP
During this point-counterpoint debate be engaged in a provocative, real-time discussion of the underlying legal issues raised by Abbott’s 2012 Citizen Petition seeking the FDA’s refusal of biosimilar applications that cite reference products for which a biologics license application (BLA) was submitted prior to the passage of the BPCIA on March 23, 2010. As the FDA continues to collect comments on Abbott’s petition, this session will address all of the hot button legal issues raised by Abbott and commenters on the other side as the panelists address the following key legal points as contemplated in the Petition –

- Whether or not information contained in the BLA is a trade secret under state and federal law
- The scope of the FDA’s biosimilar authority under the BPCIA
- The relevance of the takings clause of the Fifth Amendment and the relevance of *Ruckelshaus v. Monsanto Co.*

**10:30am  Morning Refreshment Break**

**11:00am  Understanding the Biosimilar Landscape: Addressing Emerging Regulatory and Legal Issues**

Stephen P. Benson  
Partner  
Katten Muchin Rosenman LLP

During this session hear what the emergent regulatory and legal issues are that are expected to arise from the Biologics Price Competition and Innovation Act (BPCI Act) and its implementation. Starting with a review of regulatory and legal issues that arose from the passing of the Hatch-Waxman Act that came to define the landscape for the introduction of generic versions of small molecules, the session leaders will use its example to explore the regulatory and statutory provisions of the BPCI Act that are expected to similarly evolve as the FDA implements the BPCI Act and as the courts are asked to interpret the legal operation of the law. Mr. Benson will discuss emerging, real world examples to demonstrate the current clarification and implementation of the law. Mr. Benson will conclude his presentation with a discussion of potential strategies for companies navigating the regulatory and legal framework created by the BPCI Act.
11:45am  Case Study: To Collaborate or Not to Collaborate? How Alliances and Strategic Partnerships Can Be Used to Strategically Bolster Your Patent Portfolio When Bringing a Biosimilar/Biobetter Product to Market

Bob Ward
Vice President of Strategy & Alliances, New Opportunities
AstraZeneca

During this session be engaged in a thought-provoking discussion of the pros and cons of entering the biosimilars market by way of a strategic partnership or alliance. Learn what factors can weigh in favor of and against pursuing such an endeavor as the panel discusses –

✓ Identifying up front what your business goals and objectives are within the biosimilars market and whether or not they can be reasonably achieved by entry into the market with a partner
✓ How to find the right partner based on your need – funding, clinical research, manufacturing, commercialization, regulatory support, international market expansion
✓ Quid pro quo – considering whether or not a “fair exchange” is a viable option for your biosimilars deal

12:30pm  Networking Luncheon

1:30pm  Global IP Considerations, Challenges, Risks and Opportunities for Biosimilar Applicants and Sponsors When Filing Patent Applications Abroad

Bert Oosting
Partner
Hogan Lovells LLP (Amsterdam)

During this engaging session hear from seasoned counsel with firsthand experience in navigating the patent laws of various international jurisdictions as they share and discuss proven strategies for successfully seeking and enforcing your IP rights abroad as a biosimilar applicant.

2:30pm  Afternoon Refreshment Break

3:00pm  Interactive Roundtable Discussions
**Topic 1:** Looking Beyond Year 12 – How to Ensure Your Patent Strategies Are Adding Value Beyond the Statutory Period of Exclusivity

**Topic 2:** Distinguishing Regulatory Pathways for Biosimilar Products – “Biobetter” vs. Biosimilars and Considering the Impact Your Regulatory Choice Will Have on Your IP Strategy

4:00pm **Chairs’ Closing Remarks, Open Q&A and Conference Concludes**

*Denotes Invited Speakers*