

American Conference Institute's

11th Advanced Forum on

Biotech Patents

*Comprehensive & Practical Biotech Patent Prosecution
and Litigation Strategies for an Evolving Legal Climate*

September 30 – October 1, 2009 • Royal Sonesta Hotel Boston • Boston, MA

ESTEEMED CO-CHAIRS:

Immac J. Thampoe, Ph.D.
Senior Director–Patent Law
Schering-Plough Corporation

Brian D. Coggio
Shareholder
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In this challenging time of continually evolving biotech patent jurisprudence, gain practical and effective guidance on how to:

- ◆ Adopt a practical approach to incorporating follow-on biologics into your current patent strategies
- ◆ Implement best practices for avoiding §112 and §103 rejections in light of *Kubin*, *Ariad*, and *KSR* for patenting biotech inventions including gene sequences
- ◆ Establish effective strategies to overcome charges of inequitable conduct
- ◆ Uncover ways to overcome increasing rejections related to diagnostic and treatment claims and integrate *Bilski* and related precedents into current strategies
- ◆ Design global patent strategies that take into account developing standards abroad and patent harmonization efforts
- ◆ Identify and utilize key European patent litigation strategies
- ◆ Optimize freedom to operate assessments

Featuring the post-conference Master Class:

**Drafting Successful Patent Applications
for Biotechnology Inventions**

Friday, October 2, 2009 • 9:00 am - 12:30 pm



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Bilski, Kubin, Follow-On Biologics, Patent Reform, *Tafas*...

All raise new questions and controversies
for biotech patent practitioners.

Come to the one forum that will help you revise your
strategies to adapt to new industry standards.

Emerging from a turbulent year of new case law, a resurgence of the proposed PTO rules, uncertainty associated with a new administration, and tough economic conditions, biotech patent practitioners must prepare for a new phase in this ever-evolving field. And with groundbreaking legislation regarding patent reform and follow-on biologics on the horizon, patent counsel must rise to the challenge to overcome increasing rejections, promote innovation and maximize profitability.

With this in mind, ACI's *11th Advanced Forum on Biotech Patents* once again brings together a high-caliber team of experienced biotech patent counsel who will share their collective knowledge and provide you with the most up to date strategies you can immediately incorporate into your practice.

Dedicated to the unique challenges faced by the biotech industry, your expert faculty will uncover critical insights involving:

- ◆ Developing a practical approach to follow-on biologics
- ◆ Preparing for the rule changes rising out of the *Tafas* decision
- ◆ Strategically avoiding rejection in diagnostic, method of treatment, and method of screening claims
- ◆ Delving into techniques to defeat charges of inequitable conduct
- ◆ Insights into key rule changes in foreign patent offices, including a special presentation on the EPO and EU patent litigation
- ◆ Overcoming challenges to antibody patent prosecution

Add value to your experience by attending our highly successful, interactive and in-depth Master Class on **Drafting Successful Patent Applications for Biotechnology Inventions** where you will learn how to master the art of drafting complex patent applications for your biotech inventions.

Register today to reserve your place at this timely event

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For more information about this program or our global portfolio of events, please contact:

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Group Leader & Business Development Executive
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8:00 **Registration and Continental Breakfast**9:00 **Co-Chair's Opening Remarks***Immac J. Thampoe, PhD.*

Senior Director-Patent Law

Schering-Plough Corporation (Kenilworth, New Jersey)

Brian D. Coggio

Shareholder

Fish & Richardson P.C. (New York, NY)

9:10 **Preparing for the Inevitable Enactment of Follow-on Biologics Legislation and Adopting a Practical Approach to Integrating FOB's into your Patent Strategies***Maggie Shafmaster, Ph.D.*

Sr. Vice President, Chief Patent Counsel

Genzyme Corp. (Cambridge, MA)

Barbara A. Fiacco

Partner

Foley Hoag LLP (Boston, MA)

Jeffrey P. Kushan

Partner

Sidley Austin LLP (Washington, D.C.)

As of press time, follow-on biologics legislation is under debate in the House and Senate. While awaiting the outcome, this session is designed to explore the major distinctions between the proposed legislation to gain insight into incorporating the practical application of the legislation into current patent strategies, including:

- Comparing and contrasting the Waxman and Eshoo legislative initiatives for the creation of a regulatory pathway for follow-on biologics:
 - *Access to Life Saving Medicines Act*
 - *Pathway for Biosimilars Act*
 - What are the market exclusivity terms of each?
 - Current status of the legislation
- Distinguishing the European approach to biosimilars from the U.S. legislation
 - What are the challenges faced in the European market?
 - How are they overcome, and how will the lessons learned apply to the U.S. market?
- Data exclusivity provisions:
 - understanding the data exclusivity provisions on how patents will be issued under the proposed legislation
 - what is the criteria for data exclusivity?
- What will the patent dispute resolution mechanisms be?
 - How will it differ from Hatch-Waxman litigation?
 - Notification requirements under the proposed bills
 - Understanding the timing provisions of the legislation
- Creating strategies for drafting biotech applications in the future

10:30 **Morning Refreshment Break**10:45 **Politics and Patents: Reassessing your Patent Strategy in Light of Current Changes***Michele Cimbala Ph.D.*

Director

Stern Kessler Goldstein & Fox PLLC (Washington, D.C.)

Harold C. Wegner

Partner

Foley & Lardner LLP (Washington, D.C.)

Patent reform, the new administration, evolving case law, and the current economic climate have converged on the biotech industry to create the perfect storm, catapulting biotech patent practitioners into murky waters surrounded by unknowns. This interactive session will help you to navigate the political system with an in-depth analysis of the evolving legal standards and changing players including:

- Evaluating the *Tafas* decision and the impact of the proposed PTO rules on the biotech sector
 - Predicting how *Tafas* will eventually be resolved
 - Determining what the practical application of the new PTO rules will be after *Tafas*
- Analysis of proposed patent reform legislation and its impact on the industry
- Understanding how the courts are addressing the issue of patent reform in the absence of congressional action
- Discerning the priorities of the Obama administration and the impact on biotech
 - New PTO Commissioner
 - How will the administration help to promote innovation in biotech?
- Reconciling the needs of the biotech industry with the emerging new rules
- Regulatory and Statutory Reexamination Reforms
- Incorporating deferred patent prosecution
- Strategically preparing a long-term plan to account for further reform in opposition to biotech's goals

12:00 **Networking Luncheon**1:15 **Uncovering Current Trends and Predicting Future Changes Facing Biotech Patent Practitioners***Thomas J. Filarski*

Shareholder, Chair of Chemical Group

Brinks Hofer Gilson & Lione (Chicago, IL)

Mr. Filarski will lead you through this spotlight session where he will highlight and analyze the myriad changes that have taken hold of the biotech patent industry over the past year and what practitioners can expect to see over the next 12 months.

2:00 **What's patentable? The Impact of *Bilski* and Related Precedents to Diagnostic Testing & Treatment Claims in the Biotech Patent Industry***Warren D. Woessner, J.D., Ph.D.*

Founding Shareholder

Schwegman Lundberg & Woessner (Minneapolis, MN)

Stephen Albainy-Jenei

Member

Frost Brown Todd LLC (Cincinnati, OH)

Kevin E. Noonan, Ph.D.

Partner

McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

- Analysis of emerging precedents to uncover current standards of patentability and their impact on:
 - diagnostic testing
 - method of treatment claims
 - method of screening claims
- Evaluating the standard established under *Bilski* and its implications on biotech
- *Prometheus Labs v. Mayo*
- *Classen Immunotherapies v. Biogen Idec*
- *Laboratory Corp v. Metabolite Labs, Inc.*
- Incorporating strategies to overcome the *Bilski* standard that are not too restrictive
- Asserting different types of claims as part of an overall strategy to avoid rejection
- Understanding how biotechnology companies can more effectively play in this market using its intellectual property

3:00 Afternoon Refreshment Break

3:15 Deciphering the Impact of *In re Kubin* on Application of §103 Obviousness Requirements

K. Shannon Mrksich, Ph.D.

Shareholder, Chair of Biotech Practice Group
Brinks Hofer Gilson & Lione (Chicago, IL)

Janis K. Fraser, Ph.D.

Principal

Fish & Richardson P.C. (Boston, MA)

- Analysis of the key components of the *Kubin* holding
- Overview of the Federal Circuit argument and status of potential Supreme Court review
- Reconciling the decision with the reasoning and holding in *In re Deuel*
- Application of the “obvious to try” test post *Kubin*
- Exploring the interplay between *Kubin* and *KSR*
- Considering the impact of *Kubin* on issued gene patents
- Beyond genes: how far does the *Kubin* rationale extend?

4:15 Strategies for Patenting Biotechnology Inventions with Evolving §112 Jurisprudence

Anne Brown, Ph.D.

Partner

Thompson Hine LLP (Cleveland, OH)

Jennifer Gordon, Ph.D.

Partner, Baker Botts LLP
(New York, NY)

- Incorporating *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* into current patent strategies and the impact on written description and enablement
- Defining the proper scope of the written description for biotech inventions
 - Determining when the invention is predictable enough to be described
 - Comparing method of use vs. new proteins in relation to sequence definitions

- Method claims – drafting a full written description so one can make future improvements
- Indefinite arguments under §112
- Resolving enablement concerns under Section 112
- Defeating utility rejections under Sections 101 and 112
- Balancing the tension between written description, enablement, and utility when drafting claims

5:15 Conference Adjourns for the Day

DAY TWO Thursday, October 1, 2009

8:30 Continental Breakfast

9:00 Co-Chairs' Opening Remarks

9:10 Cultivating Proactive Prosecution Strategies to Overcome Charges of Inequitable Conduct

Vineet Kohli, Esq.

Assistant Patent Counsel
Merck & Co, Inc. (Rahway, NJ)

Deborah A. Somerville

Partner

Kenyon & Kenyon LLP (New York, NY)

William C. Coppola

Head – Patent Prosecution, Bio-genomics
Sanofi-Aventis (Union, NJ)

ETHICS CREDITS

- Understanding the materiality-intent balancing standard for inequitable conduct
- Analysis of the current position of the courts
 - *McKesson v. Bridge Medical*
 - *Aventis v. Amphaster*
 - *Larson Mfg. Co. v. Aluminart Products Ltd.*
- When may intent to mislead the examiners be inferred?
- Discerning what data must be disclosed when an applicant seeks to overcome prior art by asserting unexpected results
- Understanding Rule 1.56 and the duty to disclose information material to patentability
- Developing practice steps in drafting applications to avoid allegations of inequitable conduct
 - Constructing a best-practices checklist
 - Avoiding allegations while protecting information at the insistence of the company
- Resolving claims of inequitable conduct quickly and efficiently

10:15 Morning Refreshment Break

10:30 Developing Global Biotech Patent Strategies and Identifying Key Rule Changes in Foreign Patent Offices

Lesley Rapaport MSc., LL.B.

Associate Chair, Vancouver Biotechnology Practice Group
Borden Ladner Gervais LLP (Vancouver, Canada)

Kathleen Madden Williams, Ph.D.

Partner, Co-Chair, Bio-Medical and Patent Practices
Edwards, Angell, Palmer & Dodge LLP (Boston, MA)

- Understanding the current and anticipated requirements of international patent offices:
 - Changes to the Japanese PTO
 - Securing patent protection in China
 - Biologics patent protection in India
 - Key cross-border patent issues when working with Canada
- Designing an economically sound international patent strategy to minimize risk
 - Determining which countries to pursue patent protection
 - Choosing the most cost-effective location and coordinating your efforts for long-term patent protection
- Resolving questions regarding patenting practices in multiple jurisdictions
- International harmonization update:
 - Incorporating the patent prosecution highway system
 - Damages reform
 - First to file

3:15

Freedom to Operate Assessments for the Biotech Industry

Joyce Morrison

Former VP, IP for Xencor, Inc. (Glendora, CA)

Robin N. Silva

Partner

Morgan, Lewis, & Bockius LLP (San Francisco, CA)

- Understanding when a freedom to operate analysis is necessary
- Guaranteeing the right to commercialize the IP at issue without infringing the claims of a third party
 - Identifying and analyzing potential blocking patents
 - Monitoring activity in pending 3rd party applications
 - Assessing infringement risks in biotech
 - Considering indirect infringement issues
 - Including un-issued patents and predated priority dates
- Accounting for the complexity of increasingly overlapping patents
 - Determining claim scope and what is currently pending
- Effectively conducting more elaborate search necessary for biologic compounds
- Deciding if an FTO opinion is necessary
 - Evaluating the strength of a possible opinion
 - Understanding the complexities of privilege and discovery issues relative to opinions

11:30

Spotlight Presentation: European Biotech Patent Law

In this session, Mr. Tombling and Ms. Noor will uncover the latest biotech patent strategies emerging from the EU, and share expert European litigation tactics.

Adrian Tombling

European and UK Patent Attorney

Withers & Rogers LLP (London, UK)

Marjan Noor

Partner

Howrey (London, UK)

12:30

Networking Luncheon

2:00

Tactics for Breaking Through the Challenges Associated with Antibody Patent Prosecution

Len Smith

Senior Intellectual Property Counsel

Novo Nordisk (Princeton NJ)

Dr. Hans-Rainer Jaenichen

European Patent Attorney

Vossius & Partner (Munich, Germany)

Jane Gunnison

Partner

Ropes & Gray LLP (New York, NY)

- Understanding the different types of antibody claims being issued
- Handling enablement and written description issues
 - Generic antibody claims versus species/technology-specific antibody claims
 - How to get the breadth on antibody species
 - Strategies for claiming percent homology and /or conservative substitution
- Tackling the distinct claim construction issues with antibody patents
- How are antibody claims being construed and in reference to what filing date?
- Reviewing sample antibody claims and claiming strategies
- Understanding how antibody claims are treated in Europe

3:00

Afternoon Refreshment Break

4:15

Conference Adjourns

Master Class: Friday, October 2, 2009

9:00 am-12:30 pm (*Registration begins at 8:30 am*)

Drafting Successful Patent Applications for Biotechnology Inventions

Joyce Morrison

Former VP, IP for Xencor, Inc. (Glendora, CA)

Robin N. Silva

Partner, Morgan, Lewis, & Bockius LLP (San Francisco, CA)

Anita Varma

Partner, Ropes & Gray LLP (Boston, MA)

Deirdre E. Sanders

Principal, Hamilton, Brook, Smith & Reynolds, P.C.

(Concord, MA)

In this interactive master class, your expert faculty will walk you through these increasingly complex applications, and provide you with the tools you need to draft strong applications that will be well positioned to withstand future challenges. Topics that will be covered include:

- What the examiners are looking for
- What you should include – and avoid – in drafting successful patent applications
- Addressing evolving case law and incorporating it into your claims
- Understanding when to file broad claims, when to file narrow claims
- Whether claims of different scope should be filed in the same or separate applications
- Anticipating follow-on biologic claim drafting
- Considerations for claim drafting language

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Drafting Successful Patent Applications for Biotechnology Inventions

Friday, October 2, 2009
9:00 am - 12:30 pm

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