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
Fish & Richardson P.C.

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

Register Now • 888-224-2480 • AmericanConference.com/biotechpats
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

Register now by calling 888.224.2480; by faxing your registration form to 877.927.1563; or registering online at www.AmericanConference.com/biotechpats
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

Networking Luncheon

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.

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
- Clasen 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)
- 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)
- 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

7:00 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)
- 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 Indentifying 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

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

3:15 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 third 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

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 an 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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