

American Conference Institute's 14<sup>th</sup> Advanced Forum on

# Biotech Patents

Effective and Practical Strategies for Prosecuting and Litigating Biotech Patents  
in an Increasingly Uncertain Legal Environment

Hyatt Regency Boston

November 28 – 29, 2012

Boston, MA

## Co-Chairs:



Michael J. Brignati, Ph.D.

IP Counsel

Novo Nordisk, Inc. (Princeton, NJ)



Brian Coggio

Senior Principal

Fish & Richardson, P.C.

(New York, NY)

## Experts from the USPTO:

### Keynote Speaker:



Teresa Stanek Rea

Deputy Under Secretary of

Commerce for Intellectual Property

and Deputy Director of the USPTO

United States Patent and

Trademark Office (Alexandria, VA)

George Elliott, Ph.D.

Director, TC 1600

United States Patent and Trademark Office

(Alexandria, VA)

Kathleen Fonda, Ph.D.

Senior Legal Advisor,

Office of Patent Legal Administration

United States Patent and Trademark Office

(Alexandria, VA)

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Prominent counsel from industry leaders, top biotech patent practitioners, and representatives from the USPTO and industry associations convene to share insights and advice on the latest challenges in biotechnology patenting and help you:

- **RECOGNIZE** how implementation of the America Invents Act by the USPTO will impact your practice and **PREPARE** for the upcoming **first-to-file regime**
- **ANALYZE** the outcome in *Prometheus* and its impact on personalized medicine
- **DETERMINE** the implications of the *Myriad* case for **subject matter patentability**
- **ASCERTAIN** the effects the *Akamai* and *McKesson* decisions will have on claiming **joint infringement** and their implications for diagnostic methods and more
- **EXPLORE** ways in which the *Therasense* decision has changed how patent attorneys approach **inequitable conduct** concerns
- **UTILIZE** superior techniques to better protect **antibodies** and immunological innovations
- **SCRUTINIZE** the recently issued **biosimilars pathway regulations** and **CRAFT** a winning biologic patenting strategy
- **ASSESS** how the combined evolution of **prior art obviousness** and **obvious-type double patenting** are influencing the future of secondary patents

Gain Added Learning Value by Attending the Pre- and Post-Conference Workshops:

November 28, 2012

A Interactive Working Group Session: Integrating Changes at the PTO into Biotech Patent Practices

November 30, 2012

B The Master Class on Successful and Practical Strategies for Patenting Antibody-Related Inventions

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First-to-file  
Inter Partes Review

Prometheus  
Myriad

McKesson  
The BPCIA

## What A Difference A Year Makes

The ongoing implementation of the America Invents Act and a massive upheaval of subject matter patentability signal that this continues to be a period of intense uncertainty for the biotechnology and pharmaceutical fields. Nevertheless, demand for biotech products continues to grow and innovation proceeds at a breakneck pace. To ensure that your company stays on the cutting edge, your patent strategies must evolve to meet new demands placed on your IP protection, and our forum on Biotech Patents will help you develop techniques to rise to the challenge.

ACI's **14<sup>th</sup> Advanced Forum on Biotech Patents** brings together another top-notch faculty of expert biotech patent practitioners who will share their experience and knowledge to help you avoid pitfalls and maximize the value of your intellectual property. Do not miss the opportunity to hear experienced in-house counsel and private practice attorneys share thoughts and advice on strategic patent filing and effective defense of IP rights. Topics to be discussed include:

- Analyzing the PTO's efforts to apply the America Invents Act, including how the September 16<sup>th</sup> implementation date has impacted procedure and their plans for the looming March 16<sup>th</sup> institution of the first-to-file regime.
- Investigating how the Supreme Court's *Prometheus* decision will affect personalized medicine and considering outcomes of the *Myriad* case and what that could mean for biotechnology.
- Devising a biologic patenting strategy in the wake of the FDA's newly issued biosimilar pathway regulations.

### Enhance Your Learning Experience at the Pre- and Post-Conference Workshops

To accompany your overall experience, PTO examiners and industry leaders will guide you through changes at the PTO at our in-depth pre-conference **Interactive Working Group Session: Integrating Changes at the PTO into Biotech Patent Practices**.

In addition, our post-conference **Master Class on Successful and Practical Strategies for Patenting Antibody-Related Inventions** utilizes an expert faculty to assist you in protecting and promoting products that are central to the biotech industry.

**In such uncertain times this industry-leading event is sure to sell out, so be sure to reserve your spot today.** Register now by calling **888.224.2480**; by faxing your registration form to **877.927.1563**; or register online at [www.AmericanConference.com/BiotechPatents](http://www.AmericanConference.com/BiotechPatents).

## Who You Will Meet

- Patent Attorneys
- Patent Agents
- Academics
- Business Executives

*Representing Leaders in the Field of:*

- Biotechnology Companies
- Pharmaceutical Companies
- International Pharmaceutical Companies
- Biopharmaceutical Companies

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9:00 – 12:00 | **INTERACTIVE WORKING GROUP SESSION**

**Integrating Changes at the PTO into Biotech Patent Practices**

*(Registration opens at 8:15 a.m. – Continental Breakfast will be served)*

George Elliott, Ph.D.

Director, TC 1600, United States Patent and Trademark Office (Alexandria, VA)



Michele A. Cimbala, Ph.D.

Director, Intellectual Property  
Sterne, Kessler, Goldstein & Fox, P.L.L.C. (Washington, DC)

Kathleen Fonda, Ph.D.

Senior Legal Advisor, Office of Patent Legal Administration  
United States Patent and Trademark Office (Alexandria, VA)



Esther Kepplinger

Chief Patent Counselor  
Wilson, Sonsini Goodrich, & Rosati, P.C. (Washington, DC)

*The already complex task of patent prosecution for biotech innovations is now measurably more difficult thanks to the once-in-a-generation passage of patent reform in the America Invents Act (AIA). The AIA's principle provisions are taking effect on September 16, 2012 and March 16, 2013, and the PTO must alter its procedures to reflect changes ordained by the AIA. The resulting PTO changes are forcing all parties in the patenting process, including patent examiners, to respond to the resulting increases in complexity. ACP's faculty of current and former PTO examiners will walk you through the most recent changes in PTO guidelines and consider the implications that these reforms will have on examination. You will not get this sort of on-on-one experience with PTO experts anywhere else. Stay on the cutting edge and sign up today.*

- Discussing how recent cases like *Prometheus* will impact biotech patent examination
- The continued evolution of obviousness post-KSR
  - What are the newest standards in PTO examination regarding obviousness?
  - What is the best language to use to avoid obviousness rejections at the PTO?
  - How should a response to an obviousness rejection be crafted?
- Exploring how the AIA has altered, and will alter, patent examination
  - The broadening of prior art and its effects on examination
  - How does the AIA impact biotech patent examination in particular?
- How will de-emphasis of the best mode requirement affect examination?
- Notes on the Patent Prosecution Highway (PPH)
  - How often is PPH employed today?
  - Detailing the advantages and disadvantages of the PPH
- Outlining the PTO's use of restrictions in examination
  - Describing the PTO's reasoning in restricting biotech patents
  - Methods for addressing the PTO's propensity to restrict
- Reviewing the PTO's regulations issued to the September 16<sup>th</sup> effective date and discussing the likely regulations to be issued in anticipation of the March 16, 2013 effective date

12:00 **Networking Luncheon for Working Group Attendees**

**General Session**

12:15 **Registration**

1:15 **Co-Chairs' Opening Remarks**



Michael J. Brignati, Ph.D.

IP Counsel  
Novo Nordisk, Inc.  
(Princeton, NJ)



Brian Coggio

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

1:30 **USPTO KEYNOTE: A Primer on the USPTO's Efforts to Implement the America Invents Act**



Teresa Stanek Rea

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO  
United States Patent and Trademark Office  
(Alexandria, VA)

*In this exclusive keynote address, Under Secretary Rea will discuss the actions the PTO has taken in the past year to implement elements of the AIA in anticipation of the September 16, 2012 effective date, the thought process behind the regulations issued, and how the new system is functioning thus far. In addition, she will highlight the efforts being made to issue the regulations in time for the looming March 16, 2013 effective date, including the new first-to-file regime, and how the PTO plans on dealing with what will effectively be two sets of rules governing patent applications and issued patents for the foreseeable future.*

2:30 **The Sky Is Not Falling: Protecting Your IP After *Prometheus* and *Myriad***



Michael J. Brignati, Ph.D.

IP Counsel  
Novo Nordisk, Inc.  
(Princeton, NJ)



Jasbir Sagoo, Ph.D.

Patent Attorney  
Novartis Institutes for BioMedical Research, Inc.  
(Cambridge, MA)



**Jennifer Gordon, Ph.D.**  
Partner  
Baker Botts, L.L.P.  
(New York, NY)

- Exploring the state of subject matter patentability today
  - Scrutinizing the trend narrowing the scope of subject matter patentability
  - Does the machine-or-transformation test retain any usefulness?
  - Just how useful is a “common sense” inquiry in patentability?
- Analyzing the Court’s reasoning in *Mayo v. Prometheus*
  - Considering the impact of a very broad reading of the *Prometheus* holding
  - What does the Court mean by the “routine methods” language?
  - What framework does the Court employ for determining what constitutes a “law of nature”?
  - Examining the Court’s seeming blending of 35 U.S.C. §§101, 102, and 103 in arriving at its decision
- Investigating the similarities and dissimilarities between the diagnostic method in *Prometheus* and other diagnostic methods
  - Evaluating existing diagnostic method patents in light of *Prometheus*
  - Does the *Prometheus* opinion leave room to protect other types of diagnostic methods?
  - What implications does this case have for basic method of treatment patents?
- Anticipating the *Myriad* outcome in light of *Prometheus*
  - Divining the CAFC’s analysis on remand following the *Prometheus* decision
  - Speculating on what the Supreme Court will do with the CAFC’s decision

3:45 **Refreshment Break**

4:00 **Scrutinizing the CAFC’S Decisions in *Akamai* and *McKesson* and Protecting Technology in Their Wake**



**Hans Sauer, Ph.D.**  
Deputy General Counsel for Intellectual Property  
Biotechnology Industry Organization  
(Washington, DC)



**Suzannah Sundby**  
Partner  
Smith, Gambrell & Russell, L.L.P.  
(Washington, DC)

*At press time, the Federal Circuit has yet to deliver en banc opinions in Akamai Technologies Inc. et al. v. Limelight Networks Inc. and McKesson Technologies Inc. v. Epic Systems Corp. but will have done so by the time of this conference. This session will delve into the opinions in these important cases and examine their implications, including:*

- Reviewing the decisions in *Akamai* and *McKesson*
  - Examining the CAFC’s finding on joint infringement
  - Reconsidering the single entity rule
  - How has the court defined agency in these opinions?
- Contemplating the effects of these opinions on diagnostic methods and personalized medicine
  - Are there any circumstances where actions of patients could create a joint infringement scenario?
- Evaluating the opinions’ impact on claim drafting
  - How should patents be drafted to minimize the number of steps taken in each claim?
  - Investigating steps to be taken to protect patents with claims that feature numerous steps

5:00 **Conference Adjourns to Day 2**



Cocktail Party Sponsored by:

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*Day 2: Thursday, November 29, 2012*

8:15 **Continental Breakfast**

8:45 **Co-Chairs’ Opening Remarks**

9:00 **The Complete Guide to Formulating a Biosimilars Patent Strategy Following the Implementation of the FDA’s Approval Pathway**



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



**Brenda Herschbach Jarrell, Ph.D.**  
Practice Group Leader  
Choate, Hall, & Stewart L.L.P.  
(Boston, MA)



**D. Christopher Ohly**  
Partner  
Schiff Hardin, L.L.P.  
(Washington, DC)

- Outlining the parameters of similarity in the context of large complex biological compounds
  - How do the FDA guidelines define “highly similar”?
  - Understanding the regulatory impact of differences between non-inferiority and bioequivalence
  - Ascertaining if interchangeability is possible under the guidelines
- Investigating Abbott Laboratories’ citizen’s petition to the FDA
  - Determining Abbot’s chances of success in light of *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984)

- Ensuring preparedness for biosimilars litigation
  - Putting contingency plans in place now to comply with the strict timeframes available under the statute in the face of challenges
  - Finding out which patents exist and planning for exchange requirements in the absence of an Orange Book equivalent
  - Deciding what stage it is prudent to begin researching the patent landscape surrounding a particular drug
  - Preventing litigation on platform patents and research tools
  - Exploring the possibility of licensing agreements to avoid biosimilars litigation
- Devising claim drafting methods for and against biosimilars
  - Crafting a claim strategy to head off biosimilar development
  - Writing claims to work around narrowly written biopharmaceutical patents
  - Drafting claims to stymie the creation of second-generation biologics or “bio-betters”
- Assessing the possible impact from the doctrine of equivalents on biosimilars
  - Under what circumstances will the doctrine of equivalents adversely affect a patented protein sequence?
  - Tips on drafting to avoid a doctrine of equivalents rejection by examiners

10:15 **Morning Coffee Break**

10:30 **Overcoming the Challenges and Grasping the Opportunities Presented by the PTO’s New Post-Grant Review and Inter Partes Review Procedures**



*Jeffrey Kopacz*  
Senior Patent Counsel  
Anylam Pharmaceuticals  
(Cambridge, MA)



*Robert Stoll*  
Former Commissioner for Patents  
United States Patent & Trademark Office, Partner  
Drinker Biddle, L.L.P.  
(Washington, DC)



*Robert Smyth, Ph.D.*  
Partner  
Morgan, Lewis, & Bockius, L.L.P.  
(Washington, DC)

- **Post Grant Review**
  - Weighing considerations for when a challenge should be brought under post grant review (PGR)
  - Exploring start dates, timing and basis of the application – questions to ask
    - is the challenge brought within nine months of patent issuance?
    - what is the basis of the invalidity challenge
      - prior art
      - 112 deficiency under written description

- lack of enablement
- obviousness
- inherent anticipation
- fate of best mode
- Estoppel considerations looking ahead to potential patent litigation
  - have you raised all bases for invalidity lest you be precluded from raising them in other PTO or district court proceedings?
- Examining the mechanics, protocols and procedures for PGR
  - filing of petition
  - analogous nature of proceeding to district court litigation
  - discovery
    - hearings
    - motions
    - settlement
  - appearing before the Patent Trial and Appeals Board (PTAB)
- Analyzing the petitioner’s burden of proof
  - proving that it is “more likely than not that one of the claims challenged in the petition is unpatentable”
- Procedures for appeal
- **Inter Partes Review**
  - Comparing current inter partes reexamination protocols to inter partes review protocols under AIA
  - Examining how current inter partes reexamination procedures are being employed by both patent challengers and patent holders
    - questions of economics, efficiencies and risk
    - what can we glean from these current behaviors relative to the future utilization of inter partes review?
  - Understanding the fine points of the new inter partes review procedure
    - considerations for choosing this forum
      - timing, cost, speed of resolution
  - Revisions to patent challenger’s burden of proof under current inter partes reexamination and new inter partes review procedures
    - substantial new question of patentability vs. reasonable likelihood that the petitioner will prevail on claim
    - understanding the immediate repercussions of this shift on inter partes reexam and strategies for inter partes review for pharmaceutical patent litigation
  - Discussing the impact IPR will have on intervening rights granted under 35 U.S.C. §252
    - Examining *Marine Polymer Technologies, Inc. v. Hemcon, Inc. (Fed. Cir. 2012)*
  - Exploring the scope of review for current and new procedures under 102 and 103
    - patents (prior art) and publications
    - comprehending the relationship between scope of review and estoppel

- Transition and phase out
  - examining the interplay between the timing for post grant review and inter partes review
  - transition in presiding forums
    - Central Reexam Unit (CRU) vs. Patent Trial and Appeal Board (PTAB)
    - appeal to CAFC



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



*Filko Prugo*  
Partner  
Fitzpatrick, Cella, Harper, & Scinto, L.L.P.  
(New York, NY)

12:00 **Networking Lunch**

1:15 **Understanding the Obligations and Defenses Afforded Biotech Patent Attorneys Post-*Therasense***



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



*Warren D. Woessner, Ph.D.*  
Founding Shareholder  
Schwegman, Lundberg, & Woessner, P.A.  
(Minneapolis, MN)

- Examining the Federal Circuit's tightening of the inequitable conduct standard in *Therasense v. Becton Dickson & Co.*
- Understanding how inequitable conduct is affected by patent reform
  - Supplemental proceedings under the AIA: an opportunity to cure inequitable conduct?
  - Describing the impact on life cycle planning strategies
    - Requesting a reissue
  - When is requesting a reissue a good option?
  - Will requesting a reissue allow for the opportunity to purge fraud?
- The intent to deceive standard
  - Single most reasonable inference
- Investigating the materiality standard
  - The "but for" test
- Reviewing *Pfizer v. Teva*
  - Awarding sanctions for asserting unsubstantiated claims of inequitable conduct
  - The repercussions of this ruling and its impact for future inequitable conduct filings
- Anticipating possible Supreme Court review
- Applying *Therasense* to biotech patent practice
- Taking steps to shield patent from attack when utilizing continuations and continuations in part
- Exploring how the PTO has been interpreting this ruling
  - How much has *Therasense* actually shielded practitioners from attack?

2:00 **Producing a Robust Written Description to Satisfy Ever-Shifting Requirements and Ensure Patent Validity**



*Matthew Beaudet*  
Patent Attorney  
Novartis Institutes for BioMedical Research, Inc.  
(Cambridge, MA)

- Reviewing the most recent case law on written description and enablement
  - What is the direction courts are taking on adequacy of written description?
- Balancing the tension between the need to demonstrate unpredictability to overcome an obviousness rejection and produce an adequate written description
  - Reviewing the *Eli Lilly v. Teva Pharmaceuticals* cases
- Avoiding written description problems posed by subject matter patentability requirements
- Investigating the effect of changes in the written description requirement post-*Lilly* and *Centocor* on patenting antibodies
  - What is now required in describing an antibody in a patent?
  - Detailing changes in the PTO guidelines for patenting antibodies post-*Centocor*
  - Measuring the tension between *Centocor* and *Noelle v. Lederman* in antibody patenting
- Generating best practices for producing an adequate written description for a biotech product

3:00 **Afternoon Refreshment Break**

3:15 **Crafting a Global Strategy: Best Practices for International Prosecution and Litigation to Maximize the Value of Your Biotech Patent Portfolio**



*Bert Oosting*  
Partner  
Hogan Lovells, L.L.P.  
(Amsterdam, Netherlands)



*Michael Wise*  
Chair, China Intellectual Property Practice  
Perkins Coie, L.L.P.  
(Los Angeles, CA)

- Constructing a patent prosecution strategy for EU jurisdictions
  - Charting the similarities and differences between the European and US biosimilars approval pathways
  - Considering the relative strictness of allowable antibody patent claims in the EU vis a vis the US
- Outlining strategies for how, when, and where to pursue litigation in the EU
  - What are typical issues regarding patent validity raised in EU cases?
  - Determining the European jurisdiction in which to sue
  - What can be obtained through judgments?
  - Cataloguing methods for collecting judgments in EU jurisdictions

- What is discoverable in European cases?
- Working with expert witnesses
- Exporting US evidence to the EU for litigation and vice versa
- Preparing the best position to litigate in the EU
  - Having your case ready for EU litigation
  - How does the possibility of an EU Unified Patent Court impact preparation?
- Producing a robust patenting strategy in BRIC countries
  - An update of the latest patent laws in BRIC jurisdictions
  - Understanding the importance of meeting Chinese standards to achieve global protection
  - Grasping the challenges associated with compulsory licensing statutes
  - What FCPA-related issues predominate when patenting in BRIC countries?
  - What PTE availability is there in these countries?

#### 4:15 **Demystifying the Current Obviousness Standard and Its Implications for Biotech Patenting**

*Alexander Wilson*  
Assistant General Patent Counsel  
Eli Lilly & Company, Inc.  
(Indianapolis, IN)



*John Iwanicki*  
Attorney  
Banner & Witcoff, Ltd.  
(Boston, MA)

- Exploring the reaffirmation of *KSR* though *In re Kao*
  - Understanding the impact of *KSR* and its progeny on primary compound and compositions claims
- Assessing the implications of *Otsuka Pharm. v. Sandoz*
  - Describing how *Otsuka* clarifies the obvious-type double patenting analysis
  - Determining the interplay between obvious-type double patenting analysis and traditional obviousness analysis elucidated in *Otsuka*
  - Characterizing the role of “lead compound” designation in obviousness findings
- Utilizing obvious-type double patenting claims as a litigation tool
- What is “structural” obviousness?
- Grasping the growing importance of unexpected results
  - Recognizing the tension created when emphasizing unexpected results runs up against written description requirements
- Investigating the CAFC’s trend towards granting credence towards “secondary considerations” in obviousness analysis
  - Considering the PTO’s recent embracing of secondary considerations when examining patent applications
  - Why does the CAFC weigh secondary considerations equally with unexpected results in obviousness analysis?

#### 5:15 **Conference Concludes**

*Friday, November 30, 2012*

#### 8:15 **Registration and Continental Breakfast**

#### 9:00 **The Master Class on Successful and Practical Strategies for Patenting Antibody-Related Inventions**



*Anna L. Barry, Ph.D.*  
Senior Intellectual Property Counsel  
Five Prime Therapeutics, Inc.  
(South San Francisco, CA)

*Joseph Zucchero*  
Intellectual Property Attorney  
Idera Pharmaceuticals, Inc.  
(Cambridge, MA)



*Deirdre Sanders*  
Principal  
Hamilton Brook Smith & Reynolds, P.C.  
(Concord, MA)

*Immunological innovations are central to the biotechnology industry and in light of uncertainty surrounding the patenting of genes, protecting this intellectual property is more important than ever. Nevertheless, the difficulties of antibody and other immune-related patenting have been drastically amplified in recent years. Due to the uncertainty created by trends highlighted in Prometheus and Myriad, the “obvious to try” strictures of In re Kubin, the narrowing of allowable claims by KSR and its progeny, and the heightened written description requirement in a post-Centocor v. Abbott environment, the rules for obtaining immunological patents are as complex as ever. ACI’s faculty of industry leaders will discuss the process for obtaining antibody and immune-related patents, share the latest best practices with you, and give you the chance to brainstorm with peers. Do not miss this opportunity to stay on the cutting edge.*

*Topics to be discussed include:*

- Drafting immunological claims in an increasingly hostile patenting environment
- Handling written description and enablement issues post-*Centocor v. Abbott*
- Addressing the evolving obviousness standard and its effect on antibody patenting
- Developing guidelines for drafting antibody patents when filing in Europe
- Tackling claim construction issues with antibody patents
- Considering how antibody claims can be enforced

#### 12:00 **Master Class Concludes**

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November 30, 2012

B The Master Class on Successful  
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Antibody-Related Inventions

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