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

# BIOTECH PATENTS

ANALYSIS, INSIGHTS  
and STRATEGIES  
for New Challenges in  
Biotech Patent Practice

APRIL 18 – 19, 2007

Stanford Park Hotel

Menlo Park, CA

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Allergan, Inc.  
Athersys Inc.  
Elan Pharmaceuticals, Inc.  
GeneNews  
Schering-Plough Corporation  
Vertex Pharmaceuticals Inc.

## KEYNOTE ADDRESS ON:

### NAVIGATING THE INTRACACIES OF USPTO BIOTECH PATENT PRACTICE

*John M. Whealan*  
Deputy General Counsel and  
Solicitor, United States Patent  
and Trademark Office  
(Alexandria, VA)

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Leading biotech patent practitioners and experienced in-house counsel will give you practical and tactical advice on how to:

- **DEMYSTIFY** patent reform, including the PTO rules and legislative proposals
- **INCORPORATE** new legal developments into claim construction of biotech patents
- **INTERPRET** recent inequitable conduct decisions
- **DEVELOP** strategies for patenting cutting edge biotechnology inventions
- **UNDERSTAND** the unique challenges to drafting antibody patents
- **CREATE** successful and effective biotech patent pools
- **ASSESS** the impact of recent Supreme Court attention to patent law on biotech patent practice
- **ANALYZE** the future viability of diagnostic patents
- **PREPARE** for the introduction of generic biologics
- **EXAMINE** the current status of the research patent tools exemption
- **ADDRESS** biotechnology patent concerns in a global environment



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DRAFTING SUCCESSFUL PATENT APPLICATIONS FOR  
BIOTECHNOLOGY RELATED INVENTIONS – April 20, 2007

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*Brian D. Coggio*  
Shareholder  
**Greenberg Traurig, LLP**  
(New York, NY)

*Immac J. Thampoe, Ph.D.*  
("Casey")  
Senior Director – Patent Law  
**Schering-Plough Corporation**  
(Kenilworth, NJ)

### FACULTY

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Member  
**Frost Brown Todd LLC**  
(Cincinnati, OH)

*Carl Battle*  
Senior Vice President  
& Chief Intellectual  
Property Counsel  
**Elan Pharmaceuticals, Inc.**  
(South San Francisco, CA)

*Anne Brown*  
Senior Director Intellectual  
Property **Athersys Inc.**  
(Cleveland, OH)

*John E. Burke*  
Shareholder  
**Greenberg Traurig, LLP**  
(Denver, CO)

*Michele A. Cimbala Ph.D.*  
Director  
**Sterne Kessler Goldstein &  
Fox PLLC**  
(Washington, DC)

*Lisa A. Dixon, Ph.D.*  
Patent Attorney  
**Vertex Pharmaceuticals Inc.**  
(Cambridge, MA)

*Joel B. German*  
Senior Patent Attorney,  
Legal Affairs Dept.  
**Allergan, Inc.**  
(Irvine, CA)

*James F. Haley*  
Partner, **Fish & Neave**  
(New York, NY)

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

*Cynthia L. Kanik Ph.D.*  
Of Counsel  
**Lahive & Cockfield LLP**  
(Boston, MA)

*Geoffrey M. Karny*  
Partner  
**Baker & Daniels LLP**  
(Washington, DC)

*Antoinette F. Kanski*  
Senior Counsel  
**Foley & Lardner LLP**  
(Palo Alto, CA)

*M. Veronica Mullally*  
Partner  
**Orrick, Herrington  
& Sutcliffe LLP**  
(New York, NY)

*Bert Oosting*  
Partner, **Lovells**  
(Amsterdam)

*Sander M. Rabin, M.D.*  
Chairman  
**Convergent Technology  
Patent Law Group ®**  
(Saratoga Springs, NY)

*Lesley Rapaport*  
Director of  
Intellectual Property  
**GeneNews** (Toronto, ON)

*Jane E. Remillard*  
Partner  
**Lahive & Cockfield LLP**  
(Boston, MA)

*Rochelle K. Seide, Ph.D.*  
Member, **Arent Fox PLLC**  
(New York, NY)

*Kenneth H. Sonnenfeld,*  
*Ph.D., J.D.*  
Partner  
**King & Spalding LLP**  
(New York, NY)

*Harold C. Wegner*  
Partner  
**Foley & Lardner LLP**  
(Washington, DC)

*Michael J. Wise*  
Chair of the China  
Intellectual Property  
Practice, Partner  
**Perkins Coie LLP**  
(Los Angeles, CA)

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

### WORKSHOP LEADER

*Jean B. Fordis*  
Managing Partner,  
Palo Alto Office  
**Finnegan, Henderson,  
Farabow, Garrett &  
Dunner, LLP**  
(Palo Alto, CA)

*William L. Leschensky*  
Vice President,  
Intellectual Property  
**Alexza Pharmaceuticals, Inc.**  
(Palo Alto, CA)

*Bart W. Wise*  
Senior Intellectual  
Property Counsel  
**Geron Corporation**  
(Menlo Park)

## Cut through the confusion of the myriad new challenges facing biotech patent practice

In this past year there has been a renewed interest in patent reform by Congress, the public, the PTO and now even the Supreme Court. In the already complicated world of biotech patenting, it is crucial to not only anticipate and understand this evolving legal environment but to also incorporate such change into developing and managing your biotech patent portfolio. Proposed reforms like limiting continuation and restriction practices and pending Supreme Court patent decisions could have a vast impact on strategies for filing and drafting biotech patents.

### Adapt biotech patent practices in accordance with new legal and scientific standards

If these dilemmas were not enough, there are new emerging standards developing for claim construction and still unanswered questions about the research patent tools exemption. Meanwhile, as science progresses at an increasingly rapid rate, a number of new challenges arise in relation to biotech patents. In short, anyone drafting biotech patents needs to be able to incorporate these standards, changes and scientific realities into their patents to ensure that they are not subjected to damaging future claims, both in the United States and abroad.

With all of this in mind, the American Conference Institute has developed the **8th Advanced Forum on BIOTECH PATENTS: Analysis, Insights and Strategies for New Challenges in Biotech Patent Practice** to provide you with the most up-to-date and complete information on how to incorporate the current legal developments effectively into your biotech patent practice.

Also, add value to your experience by attending our interactive Master Class: **Drafting Successful Patent Applications for Biotechnology Related Inventions**. This in-depth session will show you how to master the art of drafting complex patent applications for your biotech inventions, in addition to harnessing and maximizing their unique value.

Take this opportunity to get the most updated and comprehensive information and advice you need from leading-edge biotech patent practitioners while you network with your peers and colleagues. You also will benefit from the detailed written materials prepared specifically for this event. Reserve your spot at this invaluable conference! Register now by calling 888.224.2480; by faxing your registration form to 877.927.1563; or registering online at [www.americanconference.com/biotech](http://www.americanconference.com/biotech).

### AGENDA-AT-A-GLANCE

- ✓ Navigating the Murky Waters of Patent Reform in the Biotech Industry
- ✓ Drafting Patent Applications: Updates on Claim Construction – Enablement, Written Description, Obviousness and Utility
- ✓ Recognizing the Unique Challenges of Drafting Patents for Cutting Edge Innovations in Biotechnology
- ✓ Recognizing the Unique Challenges of Drafting Patents for Cutting Edge Innovations in Biotechnology
- ✓ Revisiting the Research Patent Tools Exemption
- ✓ Interpreting Recent Decisions Regarding Inequitable Conduct
- ✓ Planning Patent Applications with the Advent of Generic Biologics
- ✓ Diagnostic Testing – What is Patentable?
- ✓ Breaking Through the Patent Gridlock and the Return to Patent Pools
- ✓ Prosecuting Antibody Claims - Strategies for Addressing the Many Challenges
- ✓ Tackling Gene Sequences in Patents
- ✓ Applying and Avoiding the Doctrine of Inherent Anticipation
- ✓ Addressing Biotechnology Patent Issues in a Global Environment
- ✓ Roundtable Wrap Up – Reviewing the Year in Patents with an Eye Toward the Future

**7:30 Registration and Continental Breakfast**

**8:30 Co-Chairs' Opening Remarks**

*Brian D. Coggio*

Shareholder, **Greenberg Traurig, LLP** (New York, NY)

*Immac J. Thampoe, Ph.D. ("Casey")*

Senior Director – Patent Law

**Schering-Plough Corporation** (Kenilworth, NJ)

**8:45 Navigating the Murky Waters of Patent Reform in the Biotech Industry**

*Michele A. Cimbala Ph.D.*

Director

**Sterne Kessler Goldstein & Fox PLLC** (Washington, DC)

*Cynthia L. Kanik Ph.D.*

Of Counsel, **Lahive & Cockfield LLP** (Boston, MA)

There has been an extensive amount of discussion this year regarding patent reform, including the proposed USPTO rules and congressional legislation. The impact of these pending reforms is still unclear, but some of the changes could severely influence patent strategies especially in the biotechnology industry. This session will familiarize you with how the reforms could impact your patent practice.

- Understanding the proposed new PTO rules
  - review of what the rules actually say and related comments
- Examining the effect of the proposed rules on continuation practice
  - understanding the current importance of continuation practice to the biotech industry
    - fostering scientific advances
    - commercialization/protection of technological advances
    - processes and products
  - why limiting continuation practice will have specific impact on the biotechnology industry
  - impact of proposed rules on divisional deferred applications
  - exploring the options when you're not allowed continuations – appeal or abandonment
  - comparing the unlimited IPO proposed rule with RCE (Request For Continued Examination)
  - addressing concerns that limitations will result in overly broad patents
  - strategically developing your patent portfolio in light of the rule changes
    - impact on smaller biotech companies
- Analyzing restriction practice in view of the proposed reforms
  - understanding how restriction practice reforms will create a unique problem for biotech patents
    - impact on prosecution strategy
  - optimizing your argument to the PTO when your patent is restricted
    - understanding what is the actual practice v. the subjective view of the examiner
  - impact of proposed restriction rules on patent claims
  - analysis of proposed rule-making changes to Markush claims
- Investigating the proposed changes to practice for the examination of claims in patent applications
  - review of what the rules actually say and related comments

- Understanding how the combination of a limited continuation policy and the proposed changes to introduction of restriction practice curtails biotech patent strategies
  - how does the proposed accelerated examination procedure fit it?
- Reassessing your patent strategy in light of these changes
  - maximizing the breadth and scope of claims in the current environment
  - cost containment dilemmas
- Assessing the status of proposed patent reform legislation

**10:30 Morning Coffee Break**

**10:45 Drafting Patent Applications: Updates on Claim Construction – Enablement, Written Description, Obviousness and Utility**

*John P. Iwanicki*

Partner, **Banner & Witcoff Ltd.** (Boston, MA)

- Evaluating the impact of *KSR Intern. Co. v. Teleflex Inc* on the obviousness standard
  - status update
  - impact of a reversal for the biotech obviousness standard
  - will *In re Deuel* be overturned?
  - will *Papesch*-like unexpected results become more necessary?
  - obviousness rejections under Section 103
  - the motivation requirement to guard against hindsight examiner recombination of prior art
  - potential renewed prevalence of reexamination attacks on biotech patents
- Handling the tough enablement questions in the biotech industry
  - disclosing the invention in a manner sufficient to allow one of ordinary skill in the art to make and use the invention
  - resolving the uncertainty over what to include for biotechnology
  - analyzing recent case law
    - relating to vaccines
    - introduction of subjective element into enablement analysis
  - drafting effective enablement provisions when including examples of experiments on multiple species
- Defining the proper scope of written description
  - review of the *Philips* decision
    - claim is given ordinary meaning at the time of invention, as of the effective filing date
    - contrasting the need to define everything v. not defining anything
    - setting boundaries when defining things specifically
    - changing definitions as science advances
  - determining when the invention is predictable enough to be described
  - comparing method of use v. new proteins in relation to sequence definitions
  - method claims – drafting a full written description so one can make future improvements
  - indefiniteness arguments under Section 112
- Increasing lack of utility rejections in biotechnology applications
  - utility standards
- Applying Markush groups in claim construction
- Including extrinsic evidence under *Markman*

- Examining the current case law regarding claim interpretation and the scope of patent coverage
  - *Chiron v. Genentech*
  - *Kaplan v. Escher*
  - *Falco-Faulkner v. Ingels*
  - *Ariad Pharmaceuticals v. Eli Lilly* – mechanism of action

## 12:00 Networking Luncheon

### Keynote Address: Navigating the Intricacies of USPTO Biotech Patent Practice

*John M. Whealan*  
Deputy General Counsel and Solicitor  
United States Patent & Trademark Office (Alexandria, VA)

## 1:30 Recognizing the Unique Challenges of Drafting Patents for Cutting Edge Innovations in Biotechnology

*Sander M. Rabin, M.D.*  
Chairman

Convergent Technology Patent Law Group®  
(Saratoga Springs, NY)

- Overview of drafting biotech patents with new technology using RNAi (RNA Interference) as a model
  - obviousness standards
  - exploring utility and lack of utility
  - written description conundrums
  - proof of inventorship in the information age
- Creative methods for patenting bioinformatics
  - pharmacophores as patentable subject matter
  - claims in virtual biotechnology
- Genomics – claims to non-recombinant peptides and proteins
- Patents for the advancement of personalized medicine
  - effectively patenting “biomarkers” & “test and treat” technologies
- Effectively drafting patents in regenerative medicine
  - claims for stem cell-related research in the face of the seminal Thompson patents
- Patents on the biotech frontier
  - claims to chimerical human-nonhuman organisms
- Ensuring nanobiotechnology is patentable
  - dealing with convergent (cross-platform) technologies
  - claims to integrated organic-inorganic systems: microelectronic mechanical systems (MEMS) and tissues
  - exemplary claims in the nanobiotechnology of vision

## 2:15 Revisiting the Research Patent Tools Exemption

*James F. Haley*  
Partner, Fish & Neave (New York, NY)

*Joel B. German*  
Senior Patent Attorney, Legal Affairs Dept.  
Allergan, Inc. (Irvine, CA)

- Understanding what constitutes a research tool in today’s environment
- The current status of *Merck v. Integra* – where are we now?
  - questioning brightline guidance on what patented inventions are protected
  - the drug discovery process
  - therapeutic v. non-therapeutic inventions

- drugs v. methods for finding a drug v. molecule screening
- examining the current status of the reach through effect
- Analyzing safe harbor exemptions under 271(e)(1)
  - generating evidence to give to the FDA
  - defining non-infringing activity during launch
  - Hatch-Waxman and regulatory issues
  - protecting basic university research
- Differentiating between experimental use and exemptions
  - common law exemptions

## 3:15 Afternoon Refreshment Break

## 3:30 Prosecuting Antibody Claims – Strategies for Addressing the Many Challenges

*Jane E. Remillard*  
Partner, Lahive & Cockfield LLP (Boston, MA)

- 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
  - *Noelle v. Lederman* (written description is fully satisfied as long as antibody is fully characterized by its binding affinity to a specific antigen that is limited by species)
  - *Chiron v. Genentech* (patentee does not need to enable later rising technology, but can not have possession of later rising technology; the proper date for construing claims can be a moving target)
  - *Capon v. Eshbar* (written description should be determined on a case by case in view of a variety of factors, similar to enablement)
- 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

## 4:30 Planning Patent Applications with the Advent of Generic Biologics

*Rochelle K. Seide, Ph.D.*  
Member, Arent Fox PLLC (New York, NY)

- Evaluating the difficult challenges to creating generics in biotechnology
  - changing one small thing affects the entire product
- Understanding biologic manufacturers’ past reliance on two forms of exclusivity
  - patent protection *vis-à-vis* drugs in light of Hatch-Waxman
  - FDA reluctance to approve generic biologics
- Overview of the *Omnitrope* decision
  - preapproval of Omnitrope as a drug under Section 505(b)(2)
  - review of possible ANDA (Abbreviated New Drug Application) scenario for bringing a generic drug to market
  - exploring the consequences of the FDA’s approval of Omnitrope
    - isolated exception v. future approval of other follow-on biologics
- Considering the impact of generic biologics on drafting biotech applications in the future
  - matter/use purification
  - trade secrets
  - biomarkers
  - different ways to protect innovators with generics on the market
  - increased need for strategizing in drafting applications to protect the franchise

- Developing patent strategies for small molecules v. biologics
  - small molecules
    - certification
    - validation
    - infringement
    - monitoring
  - biologics
    - blocking patents for competitors
    - crystal forms/polymorphs to get their own patent protection
    - more vigorous approval

## 5:30 Conference Adjourns to Day 2

### DAY 2 – Thursday, April 19, 2007

## 8:00 Registration and Continental Breakfast

## 8:45 Co-Chairs' Remarks

## 9:00 Diagnostic Testing – What is Patentable?

*Geoffrey M. Karny*

Partner, **Baker & Daniels LLP** (Boston, MA)

*Lesley Rapaport*

Director of Intellectual Property, **GeneNews** (Toronto, ON)

- Considering the increasing importance and complexity of diagnostic testing in the biotech industry
  - rise of personalized medicine – use of multiple disease markers
  - gene and protein marker mixes
  - upsurge of testing related patents
- Addressing diagnostic testing intellectual property issues
  - are claims obtainable which are broad enough to dominate disease detection?
  - does changing one small component of a product allow one to avoid patents?
  - recent case law
- Case study – *LabCorp v. Metabolite*
  - significance of the Supreme Court's decision to let the case stand and choose to not hear it

- understanding of the lower court's rationale in upholding the patent initially held invalid
  - mental step/discovery in nature
- analysis of the Supreme Court's request that the Solicitor General brief whether a compound found in nature can be patented
  - does this suggest a desire to address the patentability of diagnostic testing?
- review and potential impact of the dissent
- analysis of what this means for the diagnostics industry
  - will this issue be raised again?
- Examination of other cases that shed light on the diagnostic patent scope
- Understanding how a diagnostics company can more effectively play in this market using its intellectual property

## 10:00 Coffee Break

## 10:15 Breaking Through the Patent Gridlock and the Return to Patent Pools

*Kenneth H. Sonnenfeld, Ph.D., J.D.*

Partner, **King & Spalding LLP** (New York, NY)

*Lisa A. Dixon, Ph.D.*

Patent Attorney, **Vertex Pharmaceuticals Inc.** (Cambridge, MA)

Currently, access to complementary technologies needed to bring a product to market is being hampered by the "patent gridlock" in biotechnology. "Patent Pools" have been effectively applied to solve this dilemma in other industries. There is every indication that it may be useful for biotechnology as well.

- Insights into the current environment
  - multiple parties owning separate patents (e.g., one person owns the sequence, another owns the protein and a third owns the structure; multiple sequences for one product owned by multiple parties)
  - royalty stacking and other dilemmas
- Understanding patent pools
  - what are they?
  - how have they been used in the past?
  - policies
- Applying patent pools to biotechnology inventions
  - how to get the parties together and reciprocally pool the patents
  - using patent pooling to deal with the patent array
  - addressing antitrust and other concerns and the cycle of competition

## 11:00 Interpreting Recent Decisions Regarding Inequitable Conduct

*John E. Burke*

Shareholder, **Greenberg Traurig, LLP** (Denver, CO)

- Understanding the two-prong standard for inequitable conduct
  - materiality
  - intent
  - the balancing act between the two
- Comparing post-1992 "materiality standard" to pre-1992 standard
- Understanding the Rule 1.56 obligations during prosecution of biotech related patent applications and its relation to inequitable conduct findings
  - disclosure to patent office
  - materiality and intent requirement
  - prosecution and litigation issues
- The troubling resurgence of decisions finding inequitable conduct
  - how experimental work was done
  - tense of words regardless of intent

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## YOU WILL MEET

Patent and IP transactional attorneys (in-house and law firm) who represent:

- biotechnology companies
- pharmaceutical companies
- biopharmaceutical companies

- Assembling data in a way that was typical for an inventor
- *Purdue* (specifications and superior invention by insight – should have told examiner this was “hype”)
- *Aventis v. Faring*
- Distilling recent CAFC decisions affirming their disdain of misrepresentations in patent cases
  - *Ferring B.V. v. Barr Laboratories, Inc.* (declaration and inequitable conduct)
  - *Novo Nordisk v. Bio-Techonology* (past versus present tense – disclosing Expected Result/prophetic examples as an Actual Result).
  - *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*
  - *Digital Control Inc., et al. v. Charles Machine Works*
  - *Pharmacia Corporation v. Par Pharmaceutical, Inc.* (a terminal disclaimer does not automatically link two patents for purposes of inequitable conduct)
  - comparing *Atofina v. Great Lakes Chemical Corp.* and *Semiconductor Energy Laboratory Co., Ltd. v. Samsung Electronics Co., Ltd.* (be careful of translations of foreign documents)
  - *M. Eagles Tool v. Fisher Tooling* (gross negligence does NOT constitute inequitable conduct)
- Discerning what data must be disclosed when an applicant seeks to overcome prior art by asserting unexpected results
- Developing practice steps in drafting applications to avoid allegations of inequitable conduct

## 12:00 Networking Luncheon

### 1:15 Tackling Gene Sequences in Patents

*Antoinette F. Konski*

Senior Counsel, **Foley & Lardner LLP** (Palo Alto, CA)

- Investigating the different ways in which DNA sequences are claimed in patents: the structure/function continuum
  - purely functional: encodes a protein with function X
  - purely structural: a single defined sequence
  - in the middle: broader structural definition around a sequence, plus a function
    - percent identity, plus function
    - up to specified number of alterations in the sequence, plus a function
    - hybridization with specified sequence
    - comprises a fragment of the specified sequence
- Addressing patentability requirements for gene patents
  - drafting written description
    - disclosing sequences of known genes
    - avoiding indefiniteness pitfalls
  - meeting the written description requirement of Section 112
  - handling enablement issues under Section 112
  - examining Section 112 indefiniteness matters
  - considering utility issues under Sections 101 and 112
  - exploring the tension between written description, enablement and utility
- Overcoming utility rejections in gene sequences
  - scientific rationale/sequence data
  - receptors/orphan receptors
- Analysis of recent federal circuit case law affecting gene sequence patents

### 2:00 Applying and Avoiding the Doctrine of Inherent Anticipation

*Warren D. Woessner*

Founding Shareholder, **Schwegman, Lundberg, Woessner & Kluth, P.A.** (Minneapolis, MN)

*Anne Brown*

Senior Director Intellectual Property, **Athersys Inc.** (Cleveland, OH)

- What are the current standards for establishing inherency?
  - is your client's new compound really new, or did the prior art inherently produce it?
  - avoiding secret prior art after *Schering v. Geneva* and *SmithKline Beecham v. Apotex*.
- When is your client's “new use of a known process” new enough to patent or is it just a newly-discovered result of an old process?
- Under what circumstances is the anticipation an “accident”?
- Patentability of processes after *Bristol-Myers Squibb v. Ben Venue* and *In re Cruciferous Sprouts Lit.*
- How “new” does a new use of an old compound need to be?
  - “making it new” – claim strategies after *Perricone v. Medicis*
- The rise (and fall?) of mechanism-of-action claims
  - *University of Rochester v. Searle* meets *Ariad v. Lilly*
  - exploring the issues
  - how to write the claim
- Methods for drafting applications that can avoid running afoul of the doctrine

## 2:45 Afternoon Refreshment Break

### 3:00 Addressing Biotechnology Patent Issues in a Global Environment

*Bert Oosting*

Partner, **Lovells** (Amsterdam)

*Michael J. Wise*

Chair of the China Intellectual Property Practice, Partner **Perkins Coie LLP** (Los Angeles, CA)

*M. Veronica Mullally*

Partner, **Orrick, Herrington & Sutcliffe LLP** (New York, NY)

## EUROPE

- New developments in Europe
  - strategies for developing a patent portfolio abroad
    - filing continuations and divisional applications: developments in the European Patent Office
    - comparing the divisional application v. continuation practice in the US
  - understanding the different priorities in the European landscape
- Handling medical use patent claims in the EU
  - 2nd medical use patent claims – “carve out” of patented indications and dosage forms for generic products
  - requiring deletion of product characteristics for authorized summary
  - differentiating from the US where the patent notice and patented indication is included in the second application for 2nd medical use
  - to what extent can you refer to the use later in the application if it's deleted?
- Implications of patenting dosage regimens in Europe
- Claiming allowances for functionality
- Comparing Europe's first to file system with U.S. opposition proceedings and interpretations
- Investigating the new European Directives and Regulations
  - clinical trial and research exemptions
  - Bolar provisions – what will the scope of Bolar be and how will it be interpreted
- Reviewing current enforcement litigation in the EU
  - cross border injunctions
  - recent decisions on claim construction
  - Germany equivalence doctrine
  - scope specifically with biotech patents

## CHINA

- Protecting IP rights in China
- Understanding the Chinese laws and regulations
  - scope of claims
  - degree of disclosure
  - scope of protection
- Assessing the most effective way to get the best possible patent protection for biotech inventions in China
- Examining the appropriate policy on human genes in China
  - Chinese guidelines for patent examination
  - knowing when genes are statutorily patentable
  - controversy regarding gene patenting in China
  - stricter standard on the industrial applicability of human genes sought for patent protection
- Exploring China's conservative view on the patentability of stem cells
- Update and impact of the ruling in Beijing upholding the Pfizer patent for Viagra

## GLOBAL ISSUES

- Efforts to harmonize international patent laws
- Genetic resources and traditional knowledge – access & benefit sharing
- Patent reforms in India
- Citizen activism

## 4:15 Roundtable Wrap Up – Reviewing the Year in Patents with an Eye Toward the Future

*Harold C. Wegner*

Partner, **Foley & Lardner LLP** (Washington, DC)

*Stephen R. Albainy-Jenei*

Member, **Frost Brown Todd LLC** (Cincinnati, OH)

*Carl Battle*

Senior Vice President & Chief Intellectual Property Counsel  
**Elan Pharmaceuticals, Inc.** (Princeton, NJ)

Industry leaders will identify, analyze, and debate the changes that have taken hold in the patent industry over the past year. We'll take a look at some of the more influential Supreme Court and Federal Circuit cases as well as the impact of patent reform. This expert panel will then tie all of the changes together and discuss what all of this means for the biotechnology industry for the future. Delegate questions and comments are welcome.

## 5:30 Conference Concludes

Friday, April 20, 2007: Master Class

## DRAFTING SUCCESSFUL PATENT APPLICATIONS FOR BIOTECHNOLOGY RELATED INVENTIONS

9:00 a.m. - 12:30 p.m. (Registration Open 8:30 a.m.)

*Jean B. Fordis*

Managing Partner, Palo Alto Office

**Finnegan, Henderson, Farabow, Garrett & Dunner, LLP**  
(Palo Alto, CA)

*William L. Leschensky*

Vice President, Intellectual Property

**Alexza Pharmaceuticals, Inc.** (Palo Alto, CA)

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Senior Intellectual Property Counsel

**Geron Corporation** (Menlo Park)

The drafting of patent applications covering biotechnology related inventions such as research tools, pharmaceuticals, genomics, proteomics and diagnostics is becoming increasingly complex, given the changing legal and public policy landscape. This is especially true considering the proposed patent reforms and concurrent legislation. Meanwhile, the PTO – following the Federal Circuit – continues to explore the application of patent law to an evolving technology. In certain cases the PTO has appeared to raise the bar by which these applications are examined and evaluated, while in others it may have been lowered.

Moreover, the rapidly evolving science and technology in this area makes it imprudent to rely upon yesterday's 'tried and true' drafting methods.

The workshop leader will walk you through the process of drafting the claims and specifications for 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 to be covered include:

- What the examiners are looking for
- What you should include – and avoid – in drafting a successful patent application in light of evolving case law and standards

- How to address Federal Circuit case law in your application proactively
- When to file broad and when to file more narrow claims
- Whether claims of differing scope should be filed in the same or separate applications
- What are we to do about biological products (nucleic acids, proteins, antibodies) that at the time of filing, can only be described functionally and not structurally
- Drafting the application to anticipate potential generic drugs and biologics
- Preparing in advance for limitations on continuations and restriction practice

In addition, the workshop will cover issues that should be considered when drafting claims in the context of litigating or licensing patent claims related to biotechnology inventions to help you prepare patents and structure deals that provide real value for your clients. Points of discussion will include:

- Consideration of claim language
  - how to permit the patentee to meet the burden of proving infringement without unnecessary difficulty
  - enablement and written description – anticipating and defending against attacks arising from these changing requirements
- Products and processes – do claims cover those products or processes that will be commercialized?

Patent practitioners and transactional lawyers will benefit from these perspectives and this hands-on approach, which will help participants not only prepare patent applications but also structure deals that will exploit the value resulting from these strong patents.

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and STRATEGIES  
for New Challenges in  
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