May 16 – 17, 2019 | Park Lane Hotel | New York, NY

17th Advanced Summit on

LIFE SCIENCES PATENTS


Insights from the USPTO:

Keynote Address: The Latest Priorities, Review Procedures and What’s New For IPR
Chief Judge, PTAB (TBA)

Analyses of New Developments in Obviousness-Type Double Patenting
Mary Till
Senior Legal Advisor
USPTO United States Patent and Trademark Office

Insights from Key Industry Leaders:

Karine Crepin
VP Head of Biologics Patents
Sanofi

Dr. Leslie Fischer
Principal Patent Attorney
Novartis Pharmaceuticals Corporation

Henry Gu
Vice President, Chief IP Counsel
Akebia Therapeutics

James Hayles
European Patent Attorney
Pfizer

Melodie Henderson
VP Intellectual Property
Sigilon Therapeutics

Immac J. Thampoe (“Casey”) Assistant General Counsel – IP Portfolio Development
Regeneron Pharmaceuticals Inc.

Nicole Woods
Vice President – Assistant General Counsel
Lilly Oncology

Yang Xu
Assistant General Counsel, IP
BeiGene Ltd

Brand New for 2019:

- Inter-Continental Considerations for Life Sciences Patent Portfolios: Developing Bullet Proof Strategies to Secure Patent Ownership in U.S. and Europe
- Antibody Patenting Think Tank: Devising Successful Patent Strategies for the U.S and Europe
- UPC and Effects of Brexit: Understanding How This May impact Your Life Sciences Patent Strategies
- Doctrine of Equivalence: Perspectives from U.S. and Europe: Utilizing the DOE Against Patent Infringement

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ACI’s 17th Advanced Summit on Life Sciences Patents returns to New York in May to provide practical insights on how to maximize your patent term and develop strategies to enhance protections for your patent portfolio.

By bringing the collective knowledge and practical experiences of leading in-house IP counsel, patent prosecutors and litigators, the USPTO, and policy experts from both sides of the Atlantic, this event will provide you with comprehensive knowledge and benchmarking opportunities to ensure that you are leading the way in patent protection for your company and clients.

Why this event is a must-attend for you and your team

- Network and benchmark with a “who’s who” of the life sciences patents community. Our unparalleled faculty features over 15 in-house counsel — including new faces from Sanofi, Pfizer, Novartis, Novo Nordisk Inc, Eli Lilly, and BeiGene Ltd. They will share practical methodologies that have worked for them in recent prosecution proceedings and provide specific advice on how to cost-effectively protect your patent portfolio.

- Benefit from direct insights from the USPTO. Hear from current and former USPTO insiders who will provide insights to help you perfect your prosecution and defense strategies.

- Participate in sophisticated and practical sessions tailored to provide comprehensive updates and strategic solutions to a savvy audience. Walk away with winning strategies you can immediately incorporate into your daily practice to address challenges with § 101 patentability, FTO searches, obviousness-type double patenting, and written description and indefiniteness.

- Obtain a globalized 360-degree view of Life Sciences Patent from the leaders setting the relevant standards. From the U.S. to Europe, this event is unparalleled in bringing together not only an exceptional in-house presence on the faculty, but also lawyers from the top IP firms representing biotechnology and pharmaceutical companies who will share their perspectives on how to thrive in challenging times.

We look forward to seeing you in New York in May. Attend this event and be part of the leading global Life Sciences community with the goal of protecting innovation in the life sciences sphere. Call 1-888-224-2480 or visit us online at www.americanconference.com/LSPatents.

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Karine Crepin
VP Head of Biologics Patents
Sanofi (Paris, France)

Dr. Leslie Fischer
Principal Patent Attorney
Novartis Pharmaceuticals Corporation (East Hanover, NJ)

Speakers

Dominic Adair
Partner
Bristows LLP
(London, United Kingdom)

Heather Boussios
Assistant General Counsel – IP
Aptevo Therapeutics
(Seattle, WA)

Melissa Brand
Associate Counsel and Director
Intellectual Property Policy
BIO (Washington, DC)

Chief Judge, PTAB (TBA)

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(Cambridge, MA)

Paul Inman
Partner
Gowlings WLG
(London, United Kingdom)

George Johnston
Counsel
Gibbons P.C. (Newark, NJ)
(Former Vice President & Chief Patent Counsel, Hoffman-LaRoche)

Forrester Liddle
Senior Director of Intellectual Property
Jounce Therapeutics
(Cambridge, MA)

Leon Lum
Intellectual Property Counsel, Legal & Corporate Affairs
Novo Nordisk Inc
(Plainsboro, NJ)

Duane Marks
Patent Counsel (Biomedicine)
Eli Lilly (Indianapolis, IN)

Stephanie Monaco
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Asha Nadipuram
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Partner
Ropes & Gray (New York, NY)

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

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Head of Legal and Intellectual Property
Kintai Therapeutics
(Cambridge, MA)

MaCharri Vorndran-Jones
Assistant General Patent Counsel
Eli Lilly and Company
(Indianapolis, IN)

Mark Waddell
Co-Chair, Life Sciences;
Chair, Patent Litigation & Counseling
Loeb & Loeb LLP
(New York, NY)

Nicole Woods
Vice President – Assistant General Patent Counsel
Novartis (Tarrytown, NY)

Yang Xu
Assistant General Counsel, IP
BeiGene Ltd (Cambridge, MA)

*Mary Till’s replacement to be announced shortly.

Join the Conversation

@ACI_Pharma #LifeSciencesPatents #DevicePatents

ACI Pharmaceutical/Biotech/Life Sciences
In this session, leading patent practitioners will provide you with a comprehensive and in-depth global IP overview to assist you in protecting your IP and minimizing risk when filing patents internationally. Benefit from our session leaders in-depth analysis of patent laws around the world on a region-by-region basis.

Topics to be discussed include:

- Comparing and contrasting the standards of patentability in the US with those at other major international patent offices
  - What is patentable?
  - Filing requirements
  - Claim construction
  - Availability of patent extensions
  - IP and regulatory data protection and exclusivity
  - Brand versus generic considerations
  - Pricing factors
  - Compulsory licensing
  - Bolar-type safe harbor provisions
  - Privilege concerns
- Going through common rejections in the US (subject matter patentability, obviousness, indefiniteness etc.) and determining how they might succeed or fail in other key international patent offices
- Procuring and enforcing life sciences patents worldwide on a cost-effective basis
  - Timing and logistics of filing: When to file to maximize exclusivity and what are the expected costs?
  - Determining the locations where it is most and least important to have patent protection in place
  - Drafting applications that satisfy the requirements of different locations
  - Coordinating between lawyers on the ground internationally and with your U.S. teams
- Spotlight on the EU: how has the establishment of a Unified Patent Court affected life sciences IP strategies?
  - How will the Court work?
  - What actions should companies take now to prepare for implementation?
  - Overview of recent EU decisions affecting life sciences
  - Keeping SPCs and PTE in mind
- Factoring in the impact of Brexit

Luncheon will be served at 12:30 pm for attendees participating in both Workshops A and B.

Registration begins at 8:00 am — Continental Breakfast will be served.

Forrester Liddle
Senior Director of Intellectual Property
Jounce Therapeutics (Cambridge, MA)

Drafting antibody claims is a complex and nuanced endeavour. Questions surrounding which claims are patentable in the United States as well as Europe are becoming increasingly difficult to navigate. This workshop will help cut through the complexity and offer solutions for successful patenting strategies as well as global commercialization. Points of discussion will include:

- Survey and review of antibody patent practice throughout the world
- Understanding different patent office’s interpretation for antibody claims
- Drafting claims for protection across different jurisdictions
- Discussing latest case law in relevant jurisdictions and interpreting their results
- Developing strategies for effectively drafting antibody claims in different international jurisdictions
- Best practices in the U.S. and Europe
- Understanding the variety of options available to maximise the scope of protection
- Practical guides and experiences
- Understanding how this process varies from country to country and office to office in certain multinational companies
- Examining the corporate in-house process for drafting claims
- Real life case-study and discussing possible solutions to common drafting dilemmas

Registration begins at 1:00 pm — Lunch will be served at 12:30 pm for attendees participating in both Workshops B and C.

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Main Conference Day 1
May 16, 2019

7:45 Registration Begins

8:30
Co-Chairs’ Opening Remarks

Karine Crepin
VP Head of Biologics Patents
Sanofi (Paris, France)

Dr. Leslie Fischer
Principal Patent Attorney
Novartis Pharmaceuticals Corporation (East Hanover, NJ)

8:45
Inter-Continental Considerations for Patent Portfolios: Devising Bullet Proof Strategies to Secure Patent Ownership in U.S. and Europe

Stephanie Monaco
Assistant General Counsel
Pfizer (Secaucus, NJ)

Marina Volin
Head of Legal and Intellectual Property
Kintai Therapeutics (Cambridge, MA)

Yang Xu
Assistant General Counsel – IP
BeiGene Ltd (Cambridge, MA)

This exclusive panel, brings together leading Patent Attorneys from both sides of the Atlantic to provide best practice strategies in securing patent ownership, assigning patent priorities documents and addressing vital considerations for patent processing at both USPTO and European Patent Office.

Points of Discussion will include:
• Developing strategies to achieving patent protection in the U.S. and Europe within one-year time frame
• Discussing cost effective processes in patent applications in U.S and Europe

9:30 USPTO Keynote Address
Examining the PTAB’s Latest Priorities, Review Procedures and New Developments Impacting IPR?

Chief Judge, PTAB (TBA)

10:45
New §101 Landscape: Exploring the Latest Developments at the PTO and District Court Relative to Patent Eligibility

Charlotte Jacobsen
Partner
Ropes & Gray

Michael Rueckheim
Partner
Winston & Stawn

Leon Lum
Intellectual Property Counsel, Legal & Corporate Affairs
Novo Nordisk Inc. (Plainsboro, NJ)

Moderator:

George Johnston
Counsel
Gibbons P.C. (Newark, NJ)
(Former Vice President & Chief Patent Counsel, Hoffman-LaRoche)

• Analyzing the USPTO’s newly released guidance on §101 and understanding its repercussions for patentability
• Examine the District Courts’ standard on §101 subject matter eligibility
• Discover whether a more stringent test is being proposed
• Exploring the patent eligibility standard for the life sciences industries
  » Exploring outcomes and certainties
• Developing best practices in drafting patent claims to avoid unpatentable subject matter findings
• Evaluate the interaction between current subject matter eligibility guidance and the Federal Circuit’s decision in Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals; 887 F.3d 1117 (Fed. Cir. 2018)
• Discover whether recent decisions are favoring towards the influence of natural derivative

11:45
Obviousness-Type Double Patenting: Safeguarding Patent Ownership Now and Facilitating the Success of Future Patent Applications

Melodie Henderson
VP Intellectual Property
Sigilon Therapeutics (Cambridge, MA)

Forrester Liddle
Senior Director of Intellectual Property
Jounce Therapeutics (Cambridge, MA)

Mary Till
Senior Legal Advisor
United States Patent and Trademark Office (Alexandria, VA)

Patent Applications
• Review of recent Federal Circuit cases related to obviousness-type double patenting
• Examining when a terminal disclaimer can be utilised to overcome an obviousness-type double patenting rejection
• Analyzing the expectations and interpretations of the patent examiners relative to the rules of obviousness-type double patenting
• Developing strategies avoid and overcome obviousness-type double patenting rejections in a collaboration setting

Patent Protection
• Analyzing key point from the Federal Circuit’s decision in Novartis AG v. Ezra Ventures LLC (Fed. Cir. 2018):
  » Discover whether the order of patent filing can make a difference relating to obviousness-type double patenting?
  » What happens if the later-expiring patent expires later that initial patent timeline because of a Patent Term Extension (PTE) awarded under 35 U.S.C. § 156
  » Clarifying the position of when are patents enforceable under 35 U.S.C. § 156 in an obviousness-type double patenting case
  » Defining the actual expiring timeline for an obviousness-type double patent with patent term extension (PTE) awarded under 35 U.S.C. § 156
Exploring the Controversy over The Use of Printed Publications in Patent Prosecution at the PTAB

Dr. Leslie Fischer  
Principal Patent Attorney  
Novartis Pharmaceuticals Corporation (East Hanover, NJ)

Interviewer:

Fikko Prugo  
Partner  
Ropes & Gray

- What is considered a printed publication at the PTAB?
- Exploring the differential treatment of printed publications in PTAB proceedings litigation and prosecution?
- Printed publications during prosecution: How applicants can leverage PTAB decisions regarding printed publications — the Office cannot have it both ways
  » Should USPTO patent examiners be required to certify printed publications in the same manner as petitioners at the PTAB?

Freedom to Operate: Evaluating Current Strategies to Avoid Future Findings of Infringement

Heather Boussios  
Assistant General Counsel – IP  
Aptevo Therapeutics (Seattle, WA)

Asha Nadipuram  
Patent Attorney  
Novartis Institutes for BioMedical (Cambridge, MA)

- Assessing the current regulatory landscape for FTO analysis
- Analyzing when during R&D third party patents discovered through FTO should be of concern
- Understanding how extensive search sequencing should be during FTO
- Seeking out the current capabilities of FTO relating to biologic patents
- Evaluating the most effective process for FTO analysis
  » Should it be in the hands of inhouse or outside counsel?


Henry Gu  
Vice President, Chief IP Counsel  
Akebia Therapeutics (Cambridge, MA)

Paul Inman  
Partner  
Gowling WLG (London, United Kingdom)

U.S.
- Analyzing case studies to develop best practice strategies for patent term extensions for maximized commercial return

Europe
- Overview and practice update on Supplementary Protection Certificates
- Gaining practical insights from Teva UK Ltd & Others v Gilead Sciences Inc (Case C 121/17)

Asia
- Clarifying the status of patent term extensions in Japan
- Reviewing examination guidelines for Patent Term Extensions in Japan

Revisiting the Doctrine of Equivalence: How to Utilize It to Prevent Patent Infringement

This brand-new Doctrine of Equivalence session will start with a brief refresher presentation on the best practice for utilising the Doctrine of Equivalence rule against patent infringement in the U.S.

A panel discussion following this will bring together most practical knowledge from both sides of the Atlantic.

Dominic Adair  
Partner  
Bristows LLP (London, United Kingdom)

Melissa Brand  
Associate Counsel and Director Intellectual Property Policy  
BIO (Washington, DC)

Barbara Ruskin  
General Counsel and Chief Patent Officer  
BA Ruskin Law LLC (Jersey City, NJ)

Mark Wadell  
Co-Chair, Life Sciences; Chair, Patent Litigation & Counseling  
Loeb & Loeb LLP (New York, NY)

USA:
- Understanding the current scope of DOE and analyzing how it may enhance a company's claim for patent infringement?
  » Recro Gainesville LLC vs. Actavis Laboratories (D. Del 2017)
- Discover how to utilize DOE to enhance both infringement and prosecution strategies
- Considerations for prosecution history estoppel for DOE

Europe:
A UK Supreme Court decision in Actavis vs. Eli Lilly [2017] UKSC 48 gave guidance on the new approach for the UK patenting process. Now, the UK Supreme Court has adopted a doctrine of equivalence (DOE) standard whereby variations to a patented product falling outside the literal scope of claims may now also be considered as infringements where the variations are “immaterial”.

Delegates will benefit from presentations regarding DOE judgements and breakdown of application currently in both USA and Europe. Additionally, receiving benchmarking opportunities:
- What are the practical results following the decision?
- Developing industry best practices to construe patents: If a product falls outside the literal scope of patent claim, can it still be considered as infringement due to immaterial variation?
- Understanding whether patents can be found as invalid from novelty claims based on 'equivalents' to prior art
- Discussing whether sufficiency attacks can succeed where the patent does not enable 'equivalents'

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Focus on Antibodies

Antibody Patent Review: Global Perspectives on Enhancing Biologic Assets Protections

Karine Crepin
VP Head of Biologics Patents
Sanofi (Paris, France)

Duane Marks
Patent Counsel (Biomedicine)
Eli Lilly (Indianapolis, IN)

Immac J. Thampoe ("Casey")
Assistant General Counsel-IP Portfolio Development
Regeneron Pharmaceuticals Inc. (Tarrytown, NY)

- Discussing the latest antibody patent case law in the U.S and Europe and interpreting their results
- Examining the scope and assessment for antibody patent protection in U.S. and Europe
  - Comparing the difference in the meaning of inherent properties
  - Understanding how to avoid issues rising from third party intervention
- Assessing the interplay between functional and structural features
- Exploring current prosecution challenges in U.S. and Europe

10:45 Networking Break

11:00

§112 Written Description Properly Circumscribing the Scope of Claims to Monoclonal Antibodies

Nicole Woods
Vice President – Assistant General Patent Counsel
Lilly Oncology (Branchburg, NJ)

PCSK9 Antibodies Update:
- Examining the Federal Circuit and District Court decisions in Amgen vs. Regeneron
- Understanding why the European Patent Office has rejected the validity of Amgen’s European patent covering PCSK9 antibodies
- Clarifying what the fundamental difference between the two different jurisdictions

Enforcement Challenges:
- Clarify the scope for obtain antibody claims
- What can be found as valid and enforceable antibody patent in US and Europe

Types of Antibody Claims:
- Understanding different the types of claims currently available for covering an antibody product from the narrowest to the broadest
- Examining the vulnerabilities for each scope of claim
- Examining the latest legal positions and challenges concerning broad and intermediate claims for antibody patents

Antibody Claims in Detail:
- Can you have a claim that resides in the entire variable antibody region of the heavy and light chain?
- What types of claims are directed towards a CVR Antibody

3:00 Networking Break
Ethical Considerations for Life Sciences Patent Prosecution

MaCharri Vorndran-Jones
Assistant General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

- Understanding how to maintain candid communication with the PTO
- Analyzing how to maintain an equitable balance between risks and benefits of asserting an inequitable conduct defence
- Exploring best practices to avoid inequitable conduct in the life sciences space: what is reasonable to disclose to the PTO going forward?
  » Related prosecution applications in the US and abroad?
  » Foreign language documents post-patent reform?
  » Related litigation, applications, and Office Actions?
  » Prior sales and prior public uses?

3:30 Conference Concludes

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17th Advanced Summit on
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