



**PROGRAM AGENDA**  
**THE UMSTEAD HOTEL & SPA**  
**CARY/RALEIGH, NC | NOVEMBER 16-18, 2015**

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**Monday, November 16, 2015**

**Registration**

**11:30 am – 3:30 pm**

*The Umstead Hotel & Spa, 100 Woodland Pond Dr, Cary, NC 27513*

Please pick up your conference badge and materials in the hotel. If you are unable to pick up your materials during this time, registration will reopen on Tuesday, November 17<sup>th</sup> at 7:30 am.

**IP Counsels Committee Business Meeting & Working Luncheon**

**12:00 pm – 3:15 pm**

*Open to IP Counsels Committee company members and their representatives only.  
Copies of the Committee Business Meeting Agenda will be provided onsite.*

**Refreshment Break**

**3:15 pm – 3:30 pm**

*Sponsored by: Marshall, Gerstein & Borun LLP*

**Pre-Conference Workshop: The Evolving Landscape of Biosimilars Litigation in the United States**

**3:30 pm – 4:30 pm**

*Sponsored by: O'Melveny & Myers, LLP*

This panel will offer an in-depth analysis of the *Amgen v. Sandoz* case. Topics to be addressed include: the Sandoz application and subsequent litigation; prospects for en banc and Supreme Court review; consequences of the Federal Circuit decision; and a look at what is next in the pipeline.

*Speakers:*

Lisa Barons Pensabene, Partner & Head of Life Sciences Litigation, O'Melveny & Myers, LLP  
Filko Prugo, Partner, O'Melveny & Myers, LLP  
Timothy Creagan, Chief Patent Counsel, Genzyme, A Sanofi Company  
Immac Thampoe, Managing IP Counsel, Biologics & Vaccines, Merck & Co.

**Welcome Reception at ORO Restaurant & Lounge**

**5:00 pm – 7:30 pm**

18 E Martin Street, Raleigh, NC

*Prior RSVP is required.*

*Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP*

Please meet in the hotel's front lobby at 5:00 pm sharp to catch a bus to the ORO Restaurant & Lounge in downtown Raleigh.

## **Tuesday, November 17, 2015**

### **Chairman's Welcome & Breakfast: Industry-University Transactions - Shrinking the Timeline**

**7:30 am – 8:30 am**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Brinks Gilson & Lione*

Get your next university deal done faster. Panelists will discuss top of mind issues in negotiating university biotechnology licenses and creative solutions.

*Moderator:* Allen Baum, Shareholder, Brinks Gilson & Lione

*Panelists:*

Kelly Sexton, PhD, Director, Office of Technology Transfer, North Carolina State University

Kimberly Parker, Global Head Legal Transactions, Novartis

Barry Myers, MD, PhD, Interim Director, Duke University Office of Licensing and Ventures

Jackie Quay, Interim Director, University of North Carolina, Office of Technology Development

### **Session 1: Antibody Drug Protection - Tale of Two Systems**

**8:45 am – 10:00 am**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Choate Hall & Stewart LLP*

More and more biotech companies are developing antibody drugs for various diseases. But protecting antibody drugs faces significant challenges both in the US and Europe. Specifically, the panel will discuss the written description challenge for broad antibody protection in the US and inventive step challenge for specific antibody protection in the Europe and explore options that biotech companies have.

*Moderator:* Fangli Chen, PhD, Partner, Choate Hall & Stewart LLP

*Panelists:*

Hugh Goodfellow, Partner, Carpmaels & Ransford

Ken Dow, Vice President, Patents & Assistant Patent Counsel, Johnson & Johnson

### **Refreshment Break**

**10:00 am – 10:15 am**

*Sponsored by: Marshall, Gerstein & Borun LLP*

### **Session 2: The Supreme Court Speaks... Again**

**10:15 am - 11:45 am**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Choate Hall & Stewart LLP*

From claim construction to Spider Man, this panel will discuss several recent Supreme Court decisions impacting the biotechnology IP community and the expected fall out from those decisions

moving forward. Issues discussed include ongoing fall out from the Court's recent Section 101 decisions; the evolving inducement standard in light of *Commil*; the state of the patent misuse doctrine in view of *Kimble v Marvel*; and claim construction after *Teva v Sandoz*.

*Moderator:* Eric Marandett, Partner, Choate Hall & Stewart LLP

*Panelists:*

Daniel Winston, Partner, Choate Hall & Stewart LLP  
Justin Huddleson, Deputy Director, IP Legal Affairs, Sanofi Pasteur  
James Harrington, Senior Vice President, Chief IP Counsel, Shire Pharmaceuticals

**Networking Luncheon**

**12:00 pm – 1:15 pm**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP*

**Session 3: Patentable Subject Matter - Where Are We Now?**

**1:30 pm – 2:45 pm**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP*

Mayo, Myriad, Sequenom—it seems as if every day another shoe drops on the ability to patent biotechnology. This session will explore the topic in depth and discuss the legal and policy implications of the current case law, including the perspective of a current judge on the Patent Trial and Appeal Board.

*Moderator:* Jennifer Swan, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

*Panelists:*

Howard Levine, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP  
Jacqueline D. Wright Bonilla, Administrative Patent Judge, Patent Trial and Appeal Board, U.S. Patent and Trademark Office  
Amanda Stark, Principal, Patent Attorney, Griffith Hack  
Virginia Campen, Assistant General Counsel, Patents, GlaxoSmithKline

**Refreshment Break**

**2:45 pm – 3:00 pm**

*Sponsored by: Marshall, Gerstein & Borun LLP*

**Session 4: The Evolution of Double Patenting**

**3:00 pm – 4:00 pm**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP*

Obviousness type double patenting was created to fill a gap in the patent statute, but it has moved beyond that narrow purpose and has worked havoc on otherwise valid and unobvious patents. This panel will discuss the recent case law of the Federal Circuit, strategies to take during prosecution to reduce risk, and legislative efforts to address this problem.

*Moderator:* Leslie McDonell, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

*Panelists:*

Bob Armitage, former Sr. Vice President & General Counsel, Eli Lilly & Company  
Nathan Edwards, PhD, IP Counsel, Biogen  
Alissa Lipton, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

**Dinner Reception at the North Carolina Museum of Natural Sciences**

**5:00 pm – 9:00 pm**

102 N Salisbury St, Raleigh, NC

Prior RSVP required

*Dinner sponsored by: McDonnell Boehnen Hulbert & Berghoff LLP*

Meet in the Hotel's lobby at 5:00 pm sharp to catch a shuttle bus to the NC Museum of Natural Sciences. Please be sure to wear your name badge. Your pass to get onto the bus is located on the back of your badge. Enjoy a scavenger hunt, followed by cocktails & dinner.

**Wednesday, November 18, 2015**

**Networking Breakfast**

**8:00 am – 9:15 am**

*The Umstead Hotel & Spa - The Umstead Ballroom*

**Session 5: Biosimilars: What We Can Expect from the European & South Korean Experience**

**9:30 am – 10:45 am**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Fitzpatrick, Cella, Harper & Scinto*

The panel will discuss foreign biosimilars patent issues and litigations to date; will consider how post-grant review proceedings have been used in the biologics context; and will compare and contrast with the U.S.; concluding with lessons learned.

*Moderator:* Christopher Borello, Partner, Fitzpatrick, Cella, Harper & Scinto

*Panelists:*

Robert Schwartz, PhD, Partner, Fitzpatrick, Cella, Harper & Scinto  
Dominic Adair, Partner, Bristows  
Kevin Kyumin Lee, Partner, Kim & Chang

**Refreshment Break**

**10:45 am – 11:00 am**

*Sponsored by: Marshall, Gerstein & Borun LLP*

## **Session 6: "Life, the Universe & Everything:" What We've Learned from IPRs in the Life Sciences**

**11:00 am – 12:15 pm**

*The Umstead Hotel & Spa - The Umstead Ballroom*

*Sponsored by: Fitzpatrick, Cella, Harper & Scinto*

In light of the handful of IPR decisions that have now completed through appeal, this panel will cover, among other things: the interface between life science litigation and IPRs; properly preparing IPR petitions to maximize potential for institution; addressing petitions effectively; tips and tactics including use of evidence, experts; what to expect concerning discovery and how to handle confidential information; the impact of IPRs on IP Strategy in the life science field; and the recent wave of third party hedge fund IPRs, their impact and the attempted responses from Congress and the USPTO.

### *Panelists:*

Claire Vasios, Vice President, IP, Alkermes, Inc.

Daniel Flint, IP Consultant, Biotechnology Industry Organization

Ha Kung Wong, Partner, Fitzpatrick, Cella, Harper & Scinto

Christina Schwarz, Partner, Fitzpatrick, Cella, Harper & Scinto

**12:15 pm: Adjournment**