

PROGRAM AGENDA THE WALDORF=ASTORIA NEW YORK, NEW YORK NOVEMBER 2-4, 2011

WEDNESDAY, NOVEMBER 2, 2011

Registration

 $11:30 \ am - 3:30 \ pm$

The Waldorf=Astoria – The Conrad Suite (4th Floor) 301 Park Avenue New York, NY 10022

Please pick up your conference badge and materials in The Waldorf=Astoria's Conrad Suite Foyer on the 4th Floor. If you are unable to pick up your materials during this time, registration will reopen on Thursday, November 3rd at 7:00 am.

IP Counsels Committee Business Meeting & Working Luncheon

 $12:00 \ pm - 3:15 \ pm$

The Waldorf=Astoria – The Conrad Suite (4th Floor) 301 Park Avenue New York, NY 10022

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

Pre-Conference Workshop:

3:30 pm - 4:30 pm

When Bad Things Happen to Good People: In House Counsel Behind Bars

The Waldorf=Astoria – The Conrad Suite (4th Floor)

Sponsored by: Foley & Lardner LLP

*Open to all registered attendees.

Although the "plague" of inequitable conduct may well be behind us, there is still much to worry about for in-house counsel. The life sciences industry's broad and varied relationships with doctors make the industry uniquely vulnerable to Foreign Corrupt Practices Act (FCPA) liability. The industry also must contend with trade embargos and anti-boycott laws. In addition, the Obama Administration has sent a message to the pharma industry that the FDA is going to be much more aggressive in its enforcement activities.

During this session panelists will review:

- How to identify risks and minimize exposure under the FCPA
- FDA's enforcement pathways and sanctions and penalties for violations of the FD&C Act
- How anti-boycott laws, and particularly the Arab League boycott of Israel, as well as the US embargo against Cuba may impact patent procurement in those countries
- How to balance running the business with the increasing need for compliance

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Moderator: Carol Stratford, Ph.D., General Counsel and Head of Intellectual Property, KaloBios Pharmaceuticals, Inc.

Panelists:

David Rosen, Partner, Foley & Lardner LLP Jaime Guerrero, Partner, Foley & Lardner LLP

Welcome Reception

 $5:30 \ pm - 7:30 \ pm$

The Campbell Apartment
15 Vanderbilt Avenue
New York, NY 10017
*Prior RSVP is required.

The Campbell Apartment

Please join us at 5:10 pm in the Waldorf=Astoria hotel lobby, where we will gather before walking to The Campbell Apartment. This intimate reception venue is located above the Grand Central Terminal and was once the office and salon of 1920s mogul John W. Campbell. The space is fully refurbished and revives the lifestyle of the Prohibition era.

Welcome Reception Sponsored by:



THURSDAY, NOVEMBER 3, 2011

Chairman's Welcome & Breakfast Buffet Patent Reform Implementation

 $7:00 \ am - 8:00 \ am$

The Waldorf=Astoria - Peacock Alley Private Dining Room (Lobby Level)

Guest Speaker:

Janet Gongola, Associate Solicitor, U.S. Patent and Trademark Office

Session 1: 8:00 am – 9:30 am

What Will Patent Reform Mean to You?

The Waldorf=Astoria – The Metropolitan Suite (18th Floor)

Sponsored by: Woodcock Washburn LLP

The panelists will draw on their many years of experience in discussing how Patent Reform will affect the biotechnology and pharmaceutical industries as well as the USPTO. Topics will include an overview of the significant changes brought on by Patent Reform including the advent of the first-to-file system, changes to the definition of prior art in 35 U.S.C. 102, changes to the existing post-grant reviews available in the USPTO as well as the new Inter Partes Review and Post-Grant Review, and the transition of the Board of Patent Appeals and Interferences to the Patent Trial and Appeal Board.

Moderator: William F. Smith, Of Counsel, Woodcock Washburn LLP

Panelists:

Charles M. Kinzig, Vice President, Corporate IP, GlaxoSmithKline Hans Sauer, Deputy General Counsel, Intellectual Property, BIO Bruce H. Stoner, Jr., Of Counsel, Greenblum & Bernstein, P.L.C.

Session 2: 9:45 am – 11:00 am

Patent Cancellation Proceedings

The Waldorf=Astoria – The Metropolitan Suite (18th Floor)

Sponsored by: Woodcock Washburn LLP

The availability of new patent cancellation (opposition) proceedings has been a hotly debated topic in the various patent reform bills that have been competing in the U.S. for the last several years. The session will address the status of oppositions in the U.S. and will also explore the various patent cancellation and opposition procedures available in various jurisdictions throughout the world.

Moderator: Joe Lucci, Partner, Woodcock Washburn LLP

Panelists:

Andrew Blattman, Ph.D., Principal, Spruson & Ferguson; Director, Ella Cheong Spruson & Ferguson

Huw Hallybone, Partner, Carpmaels and Ransford

Kristian Robinson, Director, Head of Chemical & Life Sciences, Patents, Ella Cheong Spruson & Ferguson

Session 3: 11:15 am – 11:45 am

IP Issues in Bankruptcy

The Waldorf=Astoria – The Metropolitan Suite (18th Floor) Sponsored by: Woodcock Washburn LLP

Every IP counsel in America wonders what happens when a business partner becomes insolvent and either reorganizes or liquidates in bankruptcy, but few really understand what

will happen. The speaker will walk through the issues for a licensor, for a licensee, and for a joint venture partner.

Introduction by: S. Maurice Valla, Partner, Woodcock Washburn LLP

Guest Speaker: Professor Ronald Mann, Albert E. Cinelli Enterprise Professor of Law, Co-Director, Charles E. Gerber Program in Transactional Studies, Columbia Law School

Session 4:

12:00 pm - 1:15 pm

Lunch & Guest Speaker

The Waldorf=Astoria – Peacock Alley Private Dining Room (Lobby Level) Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Guest Speaker:

Robert L. Stoll, Commissioner of Patents, U.S. Patent and Trademark Office

Session 5:

 $1:30 \ pm - 2:45 \ pm$

The Divide on Joint Infringement

The Waldorf=Astoria – The Metropolitan Suite (18th Floor) Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

This session will explore the policy and concerns behind the Federal Circuit's current divided infringement test. The panelists will discuss the current test for divided infringement, the questions asked by the Federal Circuit in the *Akamai* and *McKesson* orders for rehearing en banc, and the arguments made in the en banc briefs by the parties and the various amici.

Moderator: Howard W. Levine, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Panelists:

Daryl L. Joseffer, Partner, King & Spalding Kara F. Stoll, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Session 6:

 $3:00 \ pm - 4:00 \ pm$

What's Patentable, and How Do I Claim It?

The Waldorf=Astoria – The Metropolitan Suite (18th Floor) Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Recent decisions in U.S. federal courts have highlighted the challenges facing patent practitioners tasked with obtaining protection on subject matter directed to biomarkers. In order for the practitioner to be able to navigate this minefield, the practitioner must understand what is required for the claims to be considered patentable subject matter. But drafting the claims to recite patentable subject matter is only part of the battle; the claims must also be fully supported by the specification. To win the claim-drafting battle in the field of biomarkers, this panel will provide a primer on the requirements of patentable subject

matter, enablement, and written description, together with practical examples of representative biomarker claims.

Moderator: Mark D. Sweet, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Panelists:

Barbara B. Mittleman, M.D., Director, National Institutes of Health Public-Private Partnership Program

Mark J. Stewart, Ph.D., J.D., Senior Director, Assistant General Patent Counsel, Eli Lilly and **Company**

Small Biotech IP Forum

 $4:15 \ pm - 5:15 \ pm$

The Waldorf=Astoria – The Metropolitan Suite (18th Floor)

*Open to IP Counsels of small biotechnology companies and their representatives only. Copies of the Agenda will be provided onsite.

Dinner Reception

The Russian Tea Room 150 West 57th Street New York, NY 10019

*Prior RSVP is required.

 $7:00 \ pm - 9:00 \ pm$



THE RUSSIAN TEA ROOM

Please join us at The Russian Tea Room for an elegant dinner reception. Founded in 1927 by members of the Russian Imperial Ballet, the restaurant has always been a second home for boldface names and the intellectual elite – an exclusive enclave where actors, writers, politicians, and businessmen planned their next deals and feted their friends' latest Carnegie Hall performances.

Dinner Reception Sponsored by:



FRIDAY, NOVEMBER 4, 2011

Keynote Breakfast

 $7:30 \ am - 8:30 \ am$

IP from the Investor's Perspective

The Waldorf=Astoria - Peacock Alley Private Dining Room (Lobby Level)

Sponsored by: Choate, Hall & Stewart LLP

Guest Speaker: Owen Hughes, Director, Brookside Capital

Session 7: 8:45 am - 10:00 am

Written Description: Where Are We Now Post-Ariad?

The Waldorf=Astoria – The Metropolitan Suite (18th Floor)

Sponsored by: Choate, Hall & Stewart LLP

In 2010 the Federal Circuit sent a message with its decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* that the written description standard is here to stay and will be rigorously examined, especially in the context of biotech patents. This panel will examine how the law has evolved since *Ariad*, including application of the standard in high profile cases such as *Centocor Ortho Biotech v. Abbott Labs.* The panelists also will discuss practice pointers to avoid (or exploit) written description deficiencies and examine how analogs to the doctrine are applied overseas, particularly in Europe.

Moderator: Eric J. Marandett, Partner, Choate, Hall & Stewart LLP

Panelists:

Mathias Ricker, Ph.D., Partner, Wallinger, Ricker, Schlotter, Foerstl Kerry Flynn, Vice President, Intellectual Property, Shire Pharmaceuticals

Session 8: 10:15 am – 11:30 am

Inside the USPTO: Practical Tips for Getting Your Patent Through

The Waldorf=Astoria –The Metropolitan Suite (18th Floor)

Sponsored by: Choate, Hall & Stewart LLP

Late-stage (e.g. appeal) and post-issuance patent prosecution strategies are becoming increasingly important tools for patent applicants and patent challengers alike. This session will offer PTO perspectives on best practices for patent applicants to navigate these key procedures to best protect their IP assets. We will also provide current statistics on filings, success rates, etc.

Moderator: Brenda H. Jarrell, Ph.D., Partner, Choate, Hall & Stewart LLP

Panelists:

Judge Michael Tierney, Board of Patent Appeals, U.S. Patent and Trademark Office

11:45 am - 2:00 pm

The Waldorf=Astoria – Peacock Alley Private Dining Room (Lobby Level)
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