



PROGRAM AGENDA

CAPITAL HILTON | WASHINGTON, DC | NOVEMBER 6-8, 2013

WEDNESDAY, NOVEMBER 6, 2013

Registration

11:30 am – 3:30 pm

**Capital Hilton Hotel – Foyer 2, 2nd Floor
1001 16th Street, NW
Washington, DC 20036**

Please pick up your conference badge and materials in The Capitol Hilton Hotel's Foyer 2 on the second floor. If you are unable to pick up your materials during this time, registration will reopen on Thursday, November 7th at 7:30 am.

IP Counsels Committee Business Meeting & Working Luncheon

12:00 pm – 3:15 pm

**Capital Hilton Hotel – South American A/B, 2nd Floor
1001 16th Street, NW
Washington, DC 20036**

**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

Inter Partes Review After A Year's Worth of Experience

**Capital Hilton Hotel – South American A/B, 2nd Floor
Sponsored by: Sterne Kessler Goldstein & Fox**

This workshop will take a look back at the last year of *inter partes* review proceedings and identify strategic considerations for both patent owners and patent challengers. The panel will review the IPRs that have been filed in the life sciences, and discuss the interplay between IPRs and concurrent or prior district court litigation. In what ways has the USPTO exercised its discretion to reconsider previously-raised patentability/validity issues? How do prior arguments and determinations regarding claim construction impact an IPR? To what degree does the ability to seek to amend claims in an IPR give the patent owner an opportunity to salvage its IP rights? The panel will examine these and other issues, using case studies to give the attendees real-world examples.

Workshop Faculty:

H. Keeto Sabharwal, Director, Sterne Kessler Goldstein & Fox
Eldora Ellison, PhD, Director, Sterne Kessler Goldstein & Fox
Laurie Hill, Vice President & Deputy General Counsel, MedImmune
Maggie Shafmaster, Vice President & Chief Patent Counsel, Sanofi Pasteur

Welcome Reception

Hotel Monaco, Washington DC – Athens Room

700 F Street NW

Washington, DC 20004

*Prior RSVP is required.

5:30 pm – 7:30 pm



Please join us at 5:30 pm in the Hotel Monaco, located in the heart of downtown Washington, DC for an informal networking reception with industry colleagues.

Welcome Reception Sponsored by:

FINNEGAN

THURSDAY, NOVEMBER 7, 2013

Chairman's Welcome & Breakfast

Capital Hilton Hotel – South American A/B, 2nd Floor

Sponsored by: Fitzpatrick, Cella, Harper & Scinto

7:30 am – 8:30 am

Session 1:

Biosimilars War Games – Business and Regulatory Considerations

Capital Hilton Hotel – South American A/B, 2nd Floor

Sponsored by: Fitzpatrick, Cella, Harper & Scinto

8:45 am – 10:00 am

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated pathway for FDA approval of biosimilars. With this legislation, many new considerations have arisen for potential biosimilar applicants, which must decide whether to take advantage of this pathway or use the traditional Biologic License Application (BLA) route, and for brand pharmaceutical companies, which must now determine how to prepare for biosimilar competition. This panel will use a war games format to present these business and regulatory considerations from both the perspective of a company marketing a reference biologic and of a company marketing a biosimilar version of the reference product.

Moderator: Brian Slater, Partner, Fitzpatrick, Cella, Harper & Scinto

Panelists:

Valeta Gregg, PhD, Vice President & Associate General Counsel, Regeneron

Robert Schwartz, PhD, Partner, Fitzpatrick, Cella, Harper & Scinto

Jeff Kopacz, Senior Patent Counsel, Alnylam Pharmaceuticals

Steve Bossone, PhD, Vice President of Intellectual Property, Alnylam Pharmaceuticals

Daniel Cahoy, Professor of Business Law, Smeal College of Business, The Pennsylvania State University

Session 2:

Biosimilars War Games – Preparation for Litigation

Capital Hilton Hotel – South American A/B, 2nd Floor

Sponsored by: Fitzpatrick, Cella, Harper & Scinto

10:15 am – 11:45 am

In addition to creating an abbreviated approval pathway for biosimilars, the Biologics Price Competition and Innovation Act of 2009 outlined a complex framework for patent litigation between a biosimilar applicant and an innovator pharmaceutical company. This panel will continue the war games format from Session 1, with in-house and outside counsel for the brand and biosimilar companies navigating the various stages of this complex litigation framework.

Moderator: Brian Slater, Partner, Fitzpatrick, Cella, Harper & Scinto

Panelists:

Maggie Shafmaster, Vice President & Chief Patent Counsel, Sanofi Pasteur
Filko Prugo, Partner, Fitzpatrick, Cella, Harper & Scinto
Thomas Smith, Patent Litigation Counsel, GlaxoSmithKline
Lisa Barons Pensabene, Partner, Fitzpatrick, Cella, Harper & Scinto

Working Luncheon & Session 3:

12:00 pm – 1:15 pm

Patent Reform 2.0 – The Next Wave

Capital Hilton Hotel – South American A/B, 2nd Floor

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

Contrary to popular belief, the passage of AIA has not ended the desire from many quarters to see more patent reform. Some of the next wave of patent reform purports to address the litigation conduct of so-called Patent Assertion Entities (PAEs). Other reform proposals seek to finish some of the unfinished work from the AIA. Our distinguished panelists (the former General Counsel of Eli Lilly and Company and the Deputy Solicitor, U.S. Patent & Trademark Office) will discuss legislative ideas that have been proposed thus far, the USPTO's view of the issues, and the possible consequences for the biotechnology industry should these ideas advance into law.

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

Panelists:

Robert A. Armitage, Intellectual Property Consultant
Nathan Kelley, Deputy Solicitor, U.S. Patent & Trademark Office

Session 4: Cases to Watch

1:30 pm – 2:45 pm

Capital Hilton Hotel – South American A/B, 2nd Floor

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

In the coming year, there are many cases that have the potential to re-shape our basic understanding concerning principles of patent law. In *Akamai v. Limelight* (involving divided infringement) and *Sony Computer v. 1st Media LLC* (involving the proper test for inequitable conduct), the Supreme Court has asked for the views of the United States in determining whether to grant certiorari. In *Medtronic v. Boston Scientific Corp.*, the Supreme Court granted certiorari on the question of the correct burden of proof when a licensee challenges the infringement of a licensed patent. And the Federal Circuit has seemingly reached different conclusions concerning the bounds of the safe harbor in *Classen* and *Momenta*. Our distinguished panelists, who have both been lead counsel in patent cases before the Supreme Court and who have argued numerous appeals before the Federal Circuit, will discuss these cases and their potential impact on the biotechnology industry.

Moderator: Hans Sauer, PhD, Deputy General Counsel for IP, Biotechnology Industry Organization

Panelists:

Donald Dunner, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Charles E. Lipsey, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Keynote Speaker

3:00 pm – 4:00 pm

Capital Hilton Hotel – South American A/B, 2nd Floor

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

Guest Speaker: The Honorable Judge Kathleen M. O’Malley, Circuit Judge, U.S. Court of Appeals for the Federal Circuit

Dinner Reception

5:30 pm – 10:00 pm

Odyssey Dinner Cruise

600 Water Street, SW
Washington, DC 20024
*Prior RSVP is required.



Meet in the Capitol Hilton Hotel’s lobby at 5:30pm sharp to board a shuttle bus to this unique evening activity on the elegant, glass-enclosed Odyssey. Join us for a night of dinner, dancing and views on the Potomac. The cruise will begin boarding passengers at 6:00pm. Cocktail hour and the cruise will begin shortly thereafter. Float beneath the Memorial Bridge and past the Kennedy Center while enjoying dinner and drinks with industry colleagues. Stroll the wrap-around exterior deck for the best views of DC. After dinner, enjoy dancing and live music from a four-piece band. The cruise will dock at 10:00pm. Transportation back to the conference hotel will be provided.

FRIDAY, NOVEMBER 8, 2013

Keynote Breakfast:

8:00 am – 9:15 am

Will the International Trade Commission Remain an Expeditious Expert Forum for Patent Disputes?

Capital Hilton Hotel – South American A/B, 2nd Floor

Sponsored by: Choate Hall & Stewart LLP

During the past several years, the role of the ITC as a patent litigation forum has come under criticism in the media and in public debate. Some critics claim the ITC has become a playground for “patent trolls” and others who engage in abusive litigation practices. This has led to persistent calls to curtail the ITC’s jurisdiction and remedial powers, with negative implications for its autonomy as an independent administrative agency. Another source of policy pressure on the ITC seems to derive from high-profile disputes between large corporations that seek to exclude each other’s foreign-manufactured goods from the U.S. market. Former ITC Chairwoman Deanna Tanner Okun will provide insight on an ongoing policy debate that could affect how the ITC serves its mission of providing impartial and expeditious relief from infringing import goods, and why misguided attacks on the ITC should be of concern to the biotech industry.

Speaker: Deanna Tanner Okun, Partner, Adduci, Mastriani & Schaumberg, LLP

Session 5:

9:30 am – 10:45 am

Does Myriad Matter?

Capital Hilton Hotel – South American A/B, 2nd Floor

Sponsored by: Choate Hall & Stewart LLP

Panelists will discuss what impact the Myriad decision has had on patent examination and strategies. Has the world changed now that "isolated" DNA is officially not patentable? Are companies changing their IP strategies? Is the USPTO changing its examination approach? Has the logic of Myriad been extended to other products of nature (proteins, natural products)? Do the Myriad and Prometheus decisions together create a different value proposition for life sciences IP as contrasted with other industries? Are these decisions even meaningful, given their (necessarily?) simplistic appreciation of the technology? What should our community do, if anything, to improve the understanding that courts, administrative agencies, and/or Congress have about life sciences technologies?

Moderator: Brenda Herschbach Jarrell, PhD, Practice Group Leader, Choate Hall & Stewart LLP

Panelists:

Pamela Guy, PhD, Senior Manager of Intellectual Property, PerkinElmer

Leda Trivinos, PhD, Chief Patent Counsel, Momenta Pharmaceuticals, Inc.

Raul Tamayo, Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy, U.S. Patent & Trademark Office

Session 6:

11:00 am – 12:15 pm

Is There a New Paradigm for Indirect Infringement?

Capital Hilton Hotel – South American A/B, 2nd Floor

Sponsored by: Choate Hall & Stewart LLP

Panelists will discuss the implications of the changing legal landscape for indirect infringement. In particular, the Federal Circuit's recent decisions in cases like *Akamai v. Limelight* and *Commil v. Cisco* have raised the bar for proving joint infringement and induced infringement. The panel will review the changes in the law articulated by these cases and consider the impact on the value and enforceability of biotech patents. For example, the panel will discuss whether method of use, method of testing and method of manufacture patents still can be followed in developing and enforcing this type of patent in order to minimize the risk.

Moderator: Eric J. Marandett, Practice Group Leader & Litigation Department Co-Chair, Choate Hall & Stewart LLP

Panelists:

Wendy Plotkin, Associate General Counsel, Biogen Idec

Gregory Chopskie, Senior Counsel, Gilead Sciences, Inc.

Hugh Goodfellow, Partner, Carpmaels & Ransford