



Bio[®] IP COUNSELS COMMITTEE CONFERENCE

**PROGRAM AGENDA
RITZ-CARLTON HOTEL
NEW ORLEANS, LOUISIANA
APRIL 19-21, 2010**

MONDAY, APRIL 19, 2010

Registration

11:00 am – 4:00 pm

***Ritz Carlton – Lafayette Foyer, 2nd Floor
921 Canal Street
New Orleans, LA 70112***

Please come to pick up your conference badge and materials. If you are unable to pick up your materials during this time, registration will reopen on Tuesday, April 20th at 7:15 am in the Salon Foyer on the second floor of the Ritz-Carlton.

***IP Counsels Committee Retreat &
Working Luncheon***

12:00 pm – 4:30 pm

***Ritz Carlton – Lafayette East, 2nd Floor
921 Canal Street
New Orleans, LA 70112***

**Open to IP Counsels Committee company members and their representatives only.
Chair: Thomas Kelley, Patent Counsel, Monsanto Company
Copies of the Agenda for all Committee meetings will be provided onsite.*

Welcome Reception

5:00 pm – 8:30 pm

***New Orleans Cooking Experience
2275 Bayou Road
New Orleans, LA 70119
*Prior RSVP is required.
*Space is limited.***

Please meet in the Ritz-Carlton first floor lobby on Canal Street at 5:00 pm for shuttle transportation to the welcome reception. Shuttle will provide transportation back to hotel upon conclusion of the event.



Learn the secrets and the history of classic New Orleans cuisine in beautiful antebellum surroundings. You will learn to cook authentic Louisiana cuisine in a residential style kitchen.

Reception Sponsored by:



TUESDAY, APRIL 20, 2010

Chairman's Welcome & Breakfast Buffet

7:15 am – 8:00 am

Salon I, 2nd Floor

Sponsored by: Fenwick & West LLP

Session 1:

8:00 am – 9:45 am

Patent Pools: Navigating a Course for Access to Biotechnology Innovations

Salon II, 2nd Floor

Sponsored by: Fenwick & West LLP

Moderator:

Andrew T. Serafini, Ph.D., Partner, Fenwick & West LLP

Panelists:

James Butler, Senior Director of Intellectual Property, Sapphire Energy

Margaret Dunbar, Director of Intellectual Property Management, The Burnham Institute for Medical Research

Robert Hulse, Partner, Fenwick & West LLP

Andrew Torrance, Ph.D., Associate Professor of Law, University of Kansas School of Law

A panel of experts will explore the feasibility of biotech patent pools as a means of providing better access to biotechnology. The panel will consider the recent trends in standard settings and explore the possibility of the application of these standards to the biotech space. Some questions the panel will consider include: Are biotech patent pools a solution to fragmented IP rights & standards? Would biotech patent pools create more problems? What is the status of patent pool regulation? What are the antitrust challenges? And what are the conditions under which biotech patent pools are easy or difficult to perform?

Session 2:

10:00 am – 11:45 am

Having Your Cake and Eating It, Too—Conflicts Between Inherency and Infringement Analyses for Drug Metabolites

Salon II, 2nd Floor

Sponsored by: Fenwick & West LLP

Moderator:

Michael Shuster, Ph.D., Partner, Fenwick & West LLP

Panelists:

Hans Sauer, Ph.D., Deputy General Counsel, Intellectual Property, BIO

Andrew Torrance, Ph.D., Associate Professor of Law, University of Kansas School of Law

The panel is based on an article written by Andrew Torrance that reviews a line of cases that each reach the result of no infringement found for a claim covering a composition, when that composition is produced as a result of an in vivo transformation following drug administration.

Luncheon and Guest Speaker

12:00 pm – 1:15 pm

Health Care Reform: On the Front Lines

Salon I, 2nd Floor

Sponsored by: Foley Hoag LLP

Paul Kim, Partner, Foley Hoag LLP

Whether comprehensive health care reform is enacted in 2010 or not, the issues raised in the Congressional debate over the past 18 months will have far reaching implications for the biotechnology industry. Biosimilars, comparative effectiveness research, Medicare payment reform, coverage of drugs in the Medicare doughnut hole, support for basic research, coverage of the 47 million uninsured, fees imposed on the biopharma industry to contribute to the cost of coverage, Medicaid and Section 340 B rebates, and chronic disease and medication management programs, are just some of the initiatives that will need to be implemented quickly if a reform bill is enacted. If a bill is not enacted, these important initiatives will remain on the table for debate and ad hoc legislation in 2010 and beyond. Paul will discuss the current state of play with regard to these issues and as to health care reform generally.

Session 3:

1:30 pm – 2:45 pm

Biosimilars Legislation: A Done Deal or a Deal Undone? Part 1: Regulatory Policy

Salon II, 2nd Floor

Sponsored by: Foley Hoag LLP

Moderator:

Don Ware, Partner, Foley Hoag LLP

Panelists:

Sandi Dennis, Deputy General Counsel, Healthcare, BIO

Andrew Fox, Director, Regulatory Affairs CMC Group, Amgen

This panel will provide an overview of the expected market for biosimilars and discuss recent developments in the evolution of a regulatory pathway. The panel will also review the likely standards the FDA will apply in approving biosimilar drugs. Other important issues, such as the continued debate over data exclusivity and "evergreening" will be discussed.

Session 4:

3:00 pm – 4:00 pm

Biosimilars Legislation: A Done Deal or a Deal Undone? Part 2: Patent Enforcement

Salon II, 2nd Floor

Sponsored by: Foley Hoag LLP

Panelists:

Don Ware, Partner, Foley Hoag LLP

Gary Loeb, Vice President, Genentech

Jon Soderstrom, Ph.D., Managing Director, Yale University Office of Cooperative Research

Current proposals for biosimilars legislation take very different approaches to patent litigation against follow-on applicants, and all of the proposals differ significantly from the patent enforcement provisions in Hatch-Waxman applicable to generics. The panel will review the alternative mechanisms proposed in the House and Senate, and will address practical problems that biotech companies and academic research institutions will face in enforcing biotech patents under a biosimilars regime.

French Quarter Foot Rally

4:30 pm – 7:00 pm

**Prior RSVP is required.*

**Comfortable shoes are recommended.*

The city that has served as muse to some of the world's greatest musicians, chefs and bon vivants awaits exploration by your participants on the "Great French Quarter Foot Rally."

Attendees will meet in the Ritz-Carlton's Salon I room. Here attendees be divided into teams and provided with a scavenger hunt kit containing all necessary supplies for an adventure around the French Quarter.



Dinner Reception

August Restaurant

301 Tchoupitoulas Street

New Orleans, LA 70130

**Open to registered attendees only.*

**Prior RSVP is required.*

7:00 pm – 9:30 pm



Dinner Speaker:

Arti K. Rai, Administrator for External Affairs, US Patent and Trademark Office

In 2001, Chef John Besh opened Restaurant August in the Central Business District. August is located in an historic, four-story “French-Creole” building dating from the 1800s. Chef Besh was named one of the Ten Best New Chefs in America by Food & Wine. In 2006, he won the James Beard Foundation Award for Best Chef in the Southeast. Chef Besh competed against seven other renowned chefs in the first season of the Food Network's Iron Chef America. The cuisine at August is contemporary French with a focus on local ingredients, inspired by Besh’s classical training here and in Europe. August can be found among the highest ranking establishments in respected dining guides.

Dinner Sponsored by:



WEDNESDAY, APRIL 21, 2010

Continental Breakfast
Salon I, 2nd Floor

7:45 am – 8:45am

IP Counsels Committee Business Meeting
Salon II, 2nd Floor

8:00 am – 9:45 am

**Open to IP Counsels Committee company members and their representatives only.*

Chair: Thomas Kelley, Patent Counsel, Monsanto Company

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Session 5:

10:00 am – 11:00 am

Living on Borrowed Time: Adjustment, Extension, and Supplementary Protection of Patent Term

Salon II, 2nd Floor

Sponsored by: Alston & Bird LLP

Moderator:

Deepro Mukerjee, Partner, Alston & Bird LLP

Panelists:

Thorsten Bausch, Ph.D., Partner, Hoffmann Eitle

Nick Poulos, AVP, US Patent Litigation Attorney, sanofi-aventis

This panel will discuss the basics of patent term extension and address several current issues. Topics to be discussed include: patent term adjustment for USPTO delays under Section 154 and the status of *Wyeth v. Kappos* and related litigation; limitations and uncertainties about patent term extension for regulatory delays under Section 156; whether a patent extended under Section 156 would be infringed by a biosimilar competing product; and a primer on Supplementary Protection Certificates under European law.

Session 6: *Patenting Polynucleotides and Polypeptides*
Salon II, 2nd Floor

11:15 am – 12:00 pm

Sponsored by: *Alston & Bird LLP*

Moderator:

W. Murray Spruill, Ph.D., Partner, Alston & Bird LLP

Panelists:

Paul Cantrell, Assistant General Patent Counsel, Eli Lilly & Company

Michele Wales, Assistant General Counsel, Intellectual Property, Human Genome Sciences

Andrew Wang, Director, US Patent and Trademark Office

After *In re Kubin* we have experienced an increase in obviousness rejections relating to nucleotide and polypeptide sequences. Additionally, we face continuing written description rejections. This session will discuss these issues and focus on Examiner guidelines for patentability for nucleotide and polypeptide sequences.

Session 7: *Case Law Updates from the U.S. and Around the World* **12:15 pm – 2:00 pm**
Working Luncheon

Salon II, 2nd Floor

Sponsored by: *Alston & Bird LLP*

Moderator:

Madison Jellins, Partner, Alston & Bird LLP

Panelists:

Brian Clarke, IP Counsel, Accuray Inc.

Kathleen Fowler, Ph.D., Associate General Counsel, Amgen

Sandra Pohlman, Partner, df-mp

This panel will provide an overview of recent domestic and international case law developments, including general updates from international places of interest such as Europe and China. The panel will discuss recent U.S. case law developments, including *Ariad Pharmaceuticals, Inc. v. Eli Lilly* (written description), *i4i v. Microsoft* (damages), *Bilski v. Doll* (machine or transformation test of patent eligibility) and *Association for Molecular Pathology v. USPTO* (gene patenting), and how these cases may impact the biotechnology industry.