



PROGRAM AGENDA

CHARLESTON PLACE | CHARLESTON, SC | NOVEMBER 12-14, 2012

MONDAY, NOVEMBER 12, 2012

Registration

11:30 am – 3:30 pm

**Charleston Place – Grand Hall, Second Floor
205 Meeting Street
Charleston, SC 29401**

Please pick up your conference badge and materials in The Charleston Place Hotel's Grand Hall, outside the Live Oak Room, on the second floor. If you are unable to pick up your materials during this time, registration will reopen on Tuesday, November 13th at 7:30 am.

IP Counsels Committee Business Meeting & Working Luncheon

12:00 pm – 3:15 pm

**Charleston Place – Live Oak Room, Second Floor
205 Meeting Street
Charleston, SC 29401**

**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

Picking the Best Tools From Your Toolbox: Responding Strategically to Freedom to Operate Obstacles Under the AIA

**Charleston Place – Live Oak Room, Second Floor
Sponsored by: Sterne, Kessler, Goldstein & Fox**

This interactive workshop will focus on strategic considerations associated with launching a product under the America Invents Act (AIA) when a company does not clearly have freedom to operate. The panel will discuss various scenarios relating to the development of a product and the pros and cons of launching at risk or challenging the relevant patents in one or more post-grant proceedings. Participants in this workshop will explore the benefits and ramifications of the various patent-challenge "tools" available, such as pre-issuance submissions, post-grant review, *inter partes* review, *ex parte* reexamination or district court litigation. The panel will consider factors such as timing considerations for exercising one's options, the sizes of the companies or entities involved, the impact of the launch strategy on obtaining financing, licensing considerations and the likelihood of obtaining an injunction. The workshop will be helpful to both patent owners and parties that must navigate the IP rights of others.

Workshop Faculty:

Eldora L. Ellison, Ph.D., Director, Sterne, Kessler, Goldstein & Fox

Eric K. Steffe, Director, Sterne, Kessler, Goldstein & Fox

Todd Spalding, Assistant General Counsel, Bristol-Myers Squibb

Welcome Reception

High Cotton

199 East Bay Street

Charleston, SC 29401

**Prior RSVP is required.*

5:30 pm – 7:30 pm



Please join us at 5:15 pm in the Charleston Place hotel's lobby, where we will gather before walking to High Cotton for an informal networking reception. This high steppin' low country restaurant is located in downtown historic Charleston, just 8 minutes walk from the conference hotel.

Welcome Reception Sponsored by:

FINNEGAN

TUESDAY, NOVEMBER 13, 2012

Chairman's Welcome & Breakfast Buffet

7:30 am – 8:30 am

Unitary European Patent

Charleston Place – Live Oak Room, Second Floor

Sponsored by: Woodcock Washburn LLP

Guest Speaker: Hugh Goodfellow, Partner, Carpmaels & Ransford

A current view on the Unified Patent and the proposed new European Unified Patent Court, including how the granting and enforcement processes are intended to be implemented. Of interest to IP Counsel will be the potential pros and cons of the system for industry, including issues such as the availability of forum shopping, bifurcation of infringement and validity, and whether we might see a resurgence in the importance of national patent applications over EPO filings, potentially posing a barrier to the harmonisation that the very existence of the Unitary Patent was intended to encourage.

Session 1:

8:45 am – 10:00 am

Cases To Watch

Charleston Place – Live Oak Room, Second Floor

Sponsored by: Woodcock Washburn LLP

This is a period of great uncertainty for many legal issues of critical importance to the biotechnology community. This panel will tackle a half dozen important cases, both decided and still pending, from district courts on up through the Federal Circuit and the Supreme Court. Example topics will include

Section 271(e)(1) safe harbor, joint and induced infringement, declaratory judgment jurisdiction, patent exhaustion, and plant patents. The presentation will combine an explanation of law as it stands, possibilities for the future, and the impact on strategy and planning.

Moderator: *John F. Murphy, PhD, Associate, Woodcock Washburn LLP*

Panelists:

Amy Nelson, Associate Solicitor, U.S. Patent and Trademark Office
Erica Olson, Senior Counsel, Amgen Inc.

Session 2:

10:15 am – 11:45 am

Pitfalls and Perplexities: Special Issues in Biotech Patenting

Charleston Place – Live Oak Room, Second Floor

Sponsored by: Woodcock Washburn LLP

The panel of highly experienced patent prosecutors will focus on issues that relate to the patenting of biotechnology inventions. Topics will include requirements for written description, enablement and nonobviousness, novelty in view of inherent prior art, preparing for appeals, and recent case law that may influence strategy when prosecuting biotech inventions.

Moderator: *Peter Knudsen, PhD, Partner, Woodcock Washburn LLP*

Panelists:

Paul Golian, Assistant General Counsel, Bristol-Myers Squibb
William F. Smith, Of Counsel, Woodcock Washburn LLP, and former Administrative Patent Judge at the U.S. Patent and Trademark Office
Jean C. Witz, Supervisory Patent Examiner, Technology Center 1600, U.S. Patent and Trademark Office

Luncheon & Guest Speaker

12:00 pm – 1:15 pm

Charleston Place – Live Oak Room, Second Floor

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

Guest Speaker: *The Honorable Judge Jimmie V. Reyna, Circuit Judge, United States Court of Appeals for the Federal Circuit*

Session 3:

1:30 pm – 2:45 pm

How Do You Infringe a Pharmaceutical Method Claim?

Charleston Place – Live Oak Room, Second Floor

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

For pharmaceutical patents, direct infringement of a method patent typically occurs when a drug that is administered to a patient falls within the scope of a method claimed in a patent. To establish liability by a generic manufacturer, however, the analysis invariably focuses on the doctrine of indirect infringement, most typically induced infringement. As the generic drug has not yet been marketed at

the time of the infringement inquiry, the question of induced infringement is usually determined by review of the proposed labeling in the generic's Abbreviated New Drug Application (ANDA). A series of recent decisions by the Federal Circuit have discussed the criteria for listing method claims in the Orange Book based on the instructions in the label and the how the label can or cannot be used to establish the requisite intent to establish induced infringement. The cases discussed by the panel will include the Supreme Court's decision in *Caraco v. Novo Nordisk*, and the Federal Circuit's decisions in *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010), and *Bayer Schering v. Lupin*, 676 F.3d 1316 (Fed. Cir. April 2012).

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

Panelists:

Robert F. Shaffer, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner LLP

Charles M. Kinzig, Vice President, Global Patents, GlaxoSmithKline

Session 4:

3:00 pm – 4:00 pm

Navigating Through a Storm: Challenging Patent Term Adjustment Regulations

Charleston Place – Live Oak Room, Second Floor

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

Patent Term Adjustment (“PTA”) is a statutory mechanism for restoring patent term to applicants that was lost due to PTO delay during patent prosecution. PTA is very important for biotech and pharmaceutical companies because their patents are typically worth the most at the *end* of their patent terms. The U.S. Patent and Trademark Office (“PTO”) has promulgated regulations for calculating how much PTA patents should receive and several companies have challenged these regulations, arguing that the regulations are inconsistent with the PTA statute, and thus they are entitled to additional patent term. The panel will discuss strategies for challenging PTA regulations, including developing the best administrative record at the PTO, and litigating under the PTA statute and the Administrative Procedure Act.

Panelists:

Jennifer Johnson, Ph.D., Associate, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Jeffrey A. Lamken, Partner, Molo Lamken

Cocktail Half-Hour

5:00 pm – 5:30 pm

Charleston Place – Market Circle, First Floor

****Prior RSVP is required.***

Join your friends and industry colleagues for a cocktail from 5:00 pm – 5:30 pm, in Charleston Place Hotel's Market Circle.

Pre-Dinner Activity – Charleston Carriage Ride

5:30 pm – 6:00 pm

****Prior RSVP is required.***

Promptly at 5:30 pm, carriage rides will begin. This activity will provide a scenic tour of historic Charleston and will end at the dinner venue.

Dinner Reception

6:00 pm – 8:00 pm

Magnolia's

185 East Bay Street

Charleston, SC 29401

**Prior RSVP is required.*



Magnolia's Primrose Room is the ideal setting for a down south meal, in uptown Charleston. The room features French doors and balconies overlooking Lodge Alley and its neighboring courtyard. This dinner reception, located less than a half mile from the conference hotel, will offer a taste of the South and a chance to network with industry colleagues in a relaxed and charming setting.

WEDNESDAY, NOVEMBER 14, 2012

Breakfast Keynote

8:00 am – 9:00 am

Charleston Place – Live Oak Room, Second Floor

Sponsored by: Choate Hall & Stewart LLP

Guest Speaker: *The Honorable Judge Sally Gardner Lane, Administrative Patent Judge, Trial Division, Board of Patent Appeals and Interferences*

Judge Lane will provide an overview of the new AIA rules covering various post patent grant proceedings. Judge Lane will also discuss the current rate of case filings and the progress made on those cases. Attendees will have the opportunity to ask questions about the rules, implementation, and other aspects of post grant proceedings.

Session 5:

9:15 am – 10:45 am

The Trade Secret Minefield

Charleston Place – Live Oak Room, Second Floor

Sponsored by: Choate Hall & Stewart LLP

This panel discussion will address what biotechnology and pharmaceutical companies can do to protect themselves in the face of rising trade secret litigation, including proactive internal safeguards that companies can put in place; important considerations when entering into collaboration agreements; what recent rulings suggest about the most effective procedures for handling trade secret information; and, trade secret issues particular to the industry and how to address them.

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

Panelists:

Philip Chase, General Counsel, Adimab

Daniel Darnley, Vice President & Chief IP Counsel, Millennium: The Takeda Oncology Company

Session 6:

11:00 am – 12:15 pm

Will Prometheus & Myriad Change the World? What Do They Really Mean for the Biotechnology Industry?

Charleston Place – Live Oak Room, Second Floor

Sponsored by: Choate Hall & Stewart LLP

The life sciences industry and the intellectual property community more generally are abuzz over the potential impact of the recent *Prometheus* and *Myriad* decisions. This panel will offer perspectives from different sectors on how these seminal decisions are expected to affect their industries, the deals that are done within them, and the patent strategies they embrace.

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

Panelists:

Karla Weyand, Managing IP Counsel, Siemens Corp.

Richard Marsh, Executive Vice President, General Counsel & Secretary, Myriad Genetics, Inc.

Jean C. Witz, Supervisory Patent Examiner, Technology Center 1600, U.S. Patent and Trademark Office