



PROGRAM AGENDA
OMNI NASHVILLE HOTEL
NASHVILLE, TN | NOVEMBER 10-12, 2014

Monday, November 10, 2014

Registration

11:30 am – 3:30 pm
Omni Nashville Hotel– Cumberland Foyer
250 5th Ave S, Nashville, TN 37203

Please pick up your conference badge and materials in The Omni Nashville Hotel's Cumberland Foyer. If you are unable to pick up your materials during this time, registration will reopen on Tuesday, November 11th at 7:30 am.

IP Counsels Committee Business Meeting & Working Luncheon

12:00 pm – 3:15 pm
Omni Nashville Hotel– Cumberland 3/4 Room
250 5th Ave S, Nashville, TN 37203

**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:
Biosimilars Strategy Update**

3:30 pm – 4:30 pm
Omni Nashville Hotel– Cumberland 1/2 Room
Sponsored by: O'Melveny & Myers, LLP

The workshop will look at the available strategies, including whether to keep the dispute in the patent office (e.g., post grant review and inter partes review), have a dance (351(k)-style), or start a good old-fashioned DJ. The workshop will also discuss recent developments in these available strategies as well as how to choose and how to respond.

Moderator: Lisa Pensabene, Partner, O'Melveny & Myers, LLP

Panelists:

- Filko Prugo, Partner, O'Melveny & Myers, LLP
- Laurie L. Hill, PhD, Vice President, Intellectual Property, MedImmune
- Naomi Pearce, Global IP Consultant, Pearce IP Strategy

Welcome Reception at Wildhorse Saloon

3rd Floor

5:30 pm – 7:30 pm

120 2nd Ave N, Nashville, TN 37201

**Prior RSVP is required.*

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

Please meet in the hotel's front lobby at 5:10 pm to walk to the Welcome Reception as a group. This informal networking event will be held at the Wildhorse Saloon on the 3rd Floor from 5:30 pm - 7:30 pm. The Wildhorse Saloon is Nashville's #1 Dining and Entertainment destination and a mecca of entertainment in America. The Wildhorse is simultaneously a restaurant, bar, concert site, dance venue and TV studio.

Tuesday, November 11, 2014

Chairman's Welcome & Breakfast

7:30 am – 8:30 am

Omni Nashville Hotel– Cumberland 3/4 Room

Sponsored by: Choate Hall & Stewart LLP

Session 1:

Protecting Products of Nature

8:45 am – 10:00 am

Omni Nashville Hotel– Cumberland 1/2 Room

Sponsored by: Choate Hall & Stewart LLP

This panel will discuss how the PTO, courts, businesses and investors are responding to and applying the new PTO guidelines with respect to products of nature and the extension beyond nucleic acids.

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

Panelists:

Henry Gu, Director, Intellectual Property Counsel, Cubist Pharmaceuticals

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

Hugh Goodfellow, Partner, Carpmaels & Ransford LLP

June Cohan, Legal Advisor, Office of Patent Legal Administration, U.S. Patent & Trademark Office

Session 2:

Hot Topics: Safe Harbor, Manufacturing Patents and Patent Term Extension Pitfalls

10:15 am - 11:45 am

Omni Nashville Hotel– Cumberland 1/2 Room

Sponsored by: Choate Hall & Stewart LLP

This panel will discuss the safe harbor of 21 U.S.C. § 271(e), and its potential application to any and all patents used in the research or manufacture of pharmaceutical products based on recent and pending case law. A number of cases on the subject are currently pending before the Federal Circuit, including *Momenta v. Amphastar* and *Momenta v. Teva*. Split decisions of the Federal Circuit recently issued on the same subject in both the *Momenta v. Amphastar* and *Classen v. Biogen Idec* cases. The panel also will consider traps for the unwary in seeking and enforcing patent term extensions. The session will be a lively discussion of these difficult issues that have been the subject of several recently issued decisions and pending cases.

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

Panelists:

Daniel Winston, Partner, Choate Hall & Stewart LLP
Bruce Leicher, Senior Vice President & General Counsel, Momenta Pharmaceuticals, Inc.
Kerry Flynn, Vice President, Chief IP Property Counsel, Vertex Pharmaceuticals
James Harrington, Senior Vice President of Intellectual Property, Shire Pharmaceuticals

Luncheon Keynote

12:00 pm – 1:15 pm

Omni Nashville Hotel– Cumberland 3/4 Room

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

Speaker: Randall R. Rader, former Chief Judge, U.S. Court of Appeals for the Federal Circuit

Session 3:

An Update on ANVISA's Examination of Patent Applications in Brazil and the Status of the Unified Patent Court in Europe

1:30 pm – 2:45 pm

Omni Nashville Hotel– Cumberland 1/2 Room

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

Both Brazil and Europe are undergoing significant changes with respect to the venue for assessing patentability, validity and infringement of pharma related patents. This session will address ANVISA's (as opposed to INPI's) examination of pharmaceutical related patents in Brazil and the challenges pharmaceutical and biotech companies face in this important BRIC country. We will also provide an update on the European Unified Patent Court, including when the courts will be available for use, what can they be used for, and strategies companies should consider before utilizing this new system.

Moderator: Sanya Sukduang, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Panelists:

Anthony C. Tridico, PhD, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Leonor Galvão, PhD, Managing Partner, Murta Goyanes

Session 4:

The Evolving Landscape of Litigating Joint and Indirect Infringement

3:00 pm – 4:00 pm

Omni Nashville Hotel– Cumberland 1/2 Room

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

Method of use claims are more important than ever in the wake of *Myriad* and its progeny. But asserting method claims often involves allegations of joint and induced infringement--an area of the law that is currently in flux. The panel will discuss recent developments in the law, including the Supreme Court's recent decision in *Akamai*, and the application of the Federal Circuit's decision in *Commil* concerning evidence of "good faith." The presentation will discuss these decisions' impact and how to best counsel your client to prepare for such issues and assert claims of induced infringement.

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

Panelists:

Adam Chiss, Senior Counsel, IP Litigation, Abbvie
Bernie Greenspan, PhD, Senior Director, Intellectual Property, Prometheus Laboratories
William Raich, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Tour & Dinner Reception at The Country Music Hall of Fame

5:30 pm – 8:30 pm

222 5th Ave S, Nashville, TN 37203

*Prior RSVP required

Dinner sponsored by: McDonnell Boehnen Hulbert & Berghoff LLP

Meet in the Omni Nashville Hotel's lobby at 5:10 pm sharp to walk to the neighboring CMHF. No need to catch a cab, the conference hotel is connected on three levels to this iconic venue which will close to the public at 5:00pm. Enjoy a tour of the CMHF before drinks and dinner in the Rotunda.

Wednesday, November 12, 2014

Breakfast

8:00 am – 9:15 am

Omni Nashville Hotel– Cumberland 3/4 Room

Session 5:

Double Patenting - Double Trouble

9:30 am – 10:45 am

Omni Nashville Hotel– Cumberland 1/2 Room

Sponsored by: Fitzpatrick, Cella, Harper & Scinto

This panel will discuss recent developments in case law concerning obviousness-type double patenting; litigation trends; strategies for overcoming obviousness-type double patenting rejections in the patent office; and strategies for defending against obviousness-type double patenting allegations in litigation. The panel will also provide an update on relevant proposed legislation.

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

Panelists:

Paul Golian, Vice President & Assistant General Counsel, Bristol-Myers Squibb

Jason Okun, Partner, Fitzpatrick, Cella, Harper & Scinto

Session 6:

Update on Post Grant Review and Inter Partes Review

11:00 am – 12:15 pm

Omni Nashville Hotel– Cumberland 1/2 Room

Sponsored by: Fitzpatrick, Cella, Harper & Scinto

The panel will provide an update on the latest IPR/PGR statistics and trends, including decisions on institution, requests for rehearing, discovery, motion practice and stays in parallel proceedings. The panel will discuss lessons learned from the final written decisions issued thus far and discuss IPR strategies from both patent owner and challenger perspectives.

Panelists:

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

Tom Smith, Patent Litigation Counsel, Glaxosmithkline

Justin Oliver, Partner, Fitzpatrick, Cella, Harper & Scinto

12:15 pm: Adjournment