IP Counsels Committee Conference

November 14–16, 2016 | Savannah, GA

Program as of November 4, 2016

Monday, November 14, 2016

Registration Open
11:30 am - 3:30 pm

IPCC Business Meeting & Working Luncheon
12:00 pm – 3:15 pm
**Open to IP Counsels Committee company members only*

Refreshment Break
3:15 pm – 3:30 pm
Sponsored by: Marshall, Gerstein & Borun LLP

Pre-Conference Workshop: Goliath vs. Goliath Patent Wars
3:30 pm – 4:30 pm
Sponsored by: O'Melveny & Meyers, LLP

This expert panel will address the changing landscape in pharma/biotech patent litigation that now sees the titans of the industry engaged in turf wars. Topics to be addressed include: the evolution of platform patents from methods of manufacture to molecular targets; analysis of several recent battles between big pharma, including *Gilead v. Merck* and *Amgen v. Sanofi/Regeneron*; offensive and defensive strategies involved; and possible implications on damages and injunctive relief.

Speakers:
Lisa Barons Pensabene, Partner & Head of Life Sciences Litigation, O'Melveny & Myers, LP
Will C. Autz, Counsel, O'Melveny & Myers, LP

Welcome Reception
5:30 pm – 7:30 pm
Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Tuesday, November 15

Breakfast: Patenting Innovation—An Investment in the Future
8:00 am – 9:15 am
Sponsored by: Brinks Gilson & Lione

What drives innovation? How can we fund the discovery of new life-saving therapies while improving access to medicines for existing patients? Have patents enhanced or hindered innovation in healthcare?

These are some of the questions at the heart of the biotechnology industry. In this breakfast session, Jennifer Fox of Brinks Gilson & Lione will lead an informal discussion with Ed Miseta, Chief Editor & Clinical Leader of Outsourced Pharma, on the effects of patents on innovation and how capitalism in drug discovery can affect the availability of lifesaving drugs to patients.

Guest Speaker: Ed Miseta, Chief Editor & Clinical Leader, Outsourced Pharma
With: Jennifer Fox, Shareholder, Brinks Gilson & Lione

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Session 1: 101 Update and Industry Perspectives – Bioinformatics and Diagnostics
9:30 am – 10:45 am
Sponsored by: Choate Hall & Stewart LLP

On June 27, 2016, the U.S. Supreme Court denied cert. in Sequenom v. Ariosa, letting stand the Fed. Cir. decision that ruled an admittedly revolutionary medical test for detecting fetal genetic conditions in early pregnancy to be patent ineligible.

While there is support within the industry for a legislative fix to amend 35 USC 101, there is significant uncertainty how much support it would receive from a new administration and how long it would take to pass.

This panel will discuss how diagnostics companies are coping with the uncertainty brought about by recent 35 USC 101 rulings, whether/how this is changing the way they protect and enforce their IP, whether and how they are relying on trade secret protection, and other issues.

Moderator:
William Haulbrook, Ph.D., Partner, Choate Hall & Stewart
Speakers: Charles Lyon, Partner, Choate Hall & Stewart
Noam Pollack, General Counsel, Siemens
Mark Shtilerman, Senior Counsel, Deerfield Management

Refreshment Break
10:45 am – 11:00 am
Sponsored by: Marshall, Gerstein & Borun LLP

Session 2: Licensing & Collaboration Agreements - Traps for the Unwary
11:00 am – 12:15 pm
Sponsored by: Choate Hall & Stewart LLP

In an increasing integrated world where more and more R&D is done by collaboration, in licensing and acquisition, agreement structure can have a profound impact on the strength of IP protection. This panel will explore key issues and problems that commonly arise in license and collaboration agreements including, for example, know-how transfer provisions, common representations and warranties, change of control, diligence limitations and other issues.

Moderator:
Eric Marandett, Partner & Co-Chair IP Litigation, Choate Hall & Stewart LLP
Speakers: Randall Morin, Assistant Chief IP Counsel, Vertex Pharmaceuticals
Gerald Quirk, Chief Legal Officer at Syros Pharmaceuticals
Christine Bellon, Senior Vice President, Legal Affairs at Relay Therapeutics, Inc.

[Luncheon] Fireside Chat: Standing on the Front Lines: Trials and Tribulations of Post Grant Proceedings
12:30 pm – 1:45 pm
Sponsored by: Goodwin Procter

The U.S. patent system has changed dramatically in the five years since the passage of the American Invents Act. One of the biggest impacts on the biotechnology sector has been changes to post-grant proceedings, which have significantly increased the opportunities to challenge and invalidate a patent.

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Given these changes, how have patent holders and challengers adjusted to the new dynamic? What have been their experiences within the system, and how have patent holders dealt with these changes?

Nick Mitrokostas of Goodwin Procter will lead an informal discussion between in-house counsel on the challenges they're companies have faced in their proceedings, expectations vs. reality, and broader speculation about the impact these proceedings will have on the life sciences.

Moderator: Nicholas K. Mitrokostas, Partner, Goodwin Procter
Speakers: Willem F.C. de Weerd, Corporate Patent Counsel, Merck Serono

Session 3: Five Years of Living with the AIA: The Impact of IPR on Pharmaceutical Patents
2:00 pm – 3:15 pm
Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

When Congress enacted the AIA five years ago, very few anticipated the significant effect post grant proceedings would have on life sciences. This panel will analyze the impact of IPR proceedings on pharmaceutical patents and litigation, considering

- Statistical trends and future implications
- Complicating issues with joinder, time-barred parties, and finality
- Effects of panel dependency and lack of precedential decisions
- Estoppel effects and strategic considerations

Moderator: Robert F. Shaffer, Attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Speakers: Nicole A. Conlon, Ph.D., Attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
David Hoffman, Ph.D., Executive Director, Intellectual Property, Parker Institute for Cancer Immunotherapy
Jim Harrington, Senior Vice President -Chief Intellectual Property Counsel, Shire Pharmaceuticals

Refreshment Break
3:15 pm – 3:30 pm
Sponsored by: Marshall, Gerstein & Borun LLP

Session 4: Biosimilars—Insights into the Patent Dance
3:30 pm – 4:45 pm
Sponsored by: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

This panel will present an update on biosimilars at the FDA and the federal courts, including a detailed analysis of recent case law.

Moderator: Howard W. Levine, Attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Speakers: Jonathan R. Davies, Ph.D., Attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Brian P. Barrett, R.Ph., Senior Director - Assistant General Patent Counsel, Eli Lilly and Company

Dinner & Reception
5:30 pm – 8:30 pm
Sponsored by: McDonnell Boehnen Hulbert & Berghoff LLP

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Wednesday, November 16

Breakfast: Strategic Decision Making in Dual PTAB and District Court Proceedings
8:00am – 9:15 am
Sponsored by: Proskauer

Inter partes reviews have transformed the relationship between Article III patent litigation and administrative patent actions. Originally intended as a substitute for district court litigation, *inter partes* reviews have proven popular as well as controversial. Yet scholarly and other analyses of litigant behavior in these proceedings has been limited thus far to descriptive data summaries or specific policy perspectives on these types of post-grant challenges, such as their impact on the well-rehearsed patent troll debate.

At this breakfast session, we will explore the impact of dual PTAB and district court proceedings in the biopharma industry through an informal discussion with two in-house counsels from leading biopharma companies and Prof. Saurabh Vishnubhakat, who conducted original research of how litigants use *inter partes* reviews relative to Article III litigation, and the implications of these latest findings for the U.S. system for adjudicating patent validity, generally, and for the biotech sector in particular.

Introduction: Fangli Chen, Proskauer Rose LLP
Interviewer: Siegmund "Sige" Gutman, Proskauer Rose LLP
Interviewees: Prof. Saurabh Vishnubhakat, Associate Professor of Law, Texas A&M University School of Law / Postdoctoral Associate, Duke Law
Karen Martin, In-house counsel, Shire
Henry H. Gu, Assistant General Counsel, Head of IP, ARIAD Pharmaceuticals

Session 5: The Effect of Brexit On The Unified Patent System, the U.K. and Global Patent Strategy
9:30 am – 10:45 am
Sponsored by: Fitzpatrick, Cella, Harper & Scinto

This panel will discuss the ramifications of Brexit on the implementation and realization of the European Unitary Patent, Unified Patent System and Unified Patent Court, and how it may affect U.K. patent practice and global patent strategy.

Moderator: Robert S. Schwartz, Ph.D., Partner, Fitzpatrick Cella Harper and Scinto
Speakers: Christopher P. Borello, Partner, Fitzpatrick Cella Harper and Scinto
Larry Coury, Ph.D., Regeneron
Dominic Adair, Ph.D., Partner, Bristows
Dirk Bühler, Ph.D., Partner, Maiwald

Refreshment Break
10:45 am – 11:00 am
Sponsored by: Marshall, Gerstein & Borun LLP

Session 6: Unique Issues for Method of Treatment Patents
11:00 am – 12:15 pm
Sponsored by: Fitzpatrick, Cella, Harper & Scinto

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This panel will discuss the state of law regarding validity, patentability and infringement of method of treatment patents. This will include looking at section 101 under the Supreme Court's Mayo analysis (such as with BMS v. Merck, Ariosa Diagnostics v. Sequenom and Vanda v. Roxane), unique section 112 issues and other potential legal issues that may, in the future, lead to Post Grant Review, particularly in light of the broader range of bases available for challenge as compared to Inter Partes Review. This will also include a look at recent decisions on indirect infringement and the impact of claim construction on the outcome of these cases.

Moderators: Ha Kung Wong, Fitzpatrick, Cella, Harper & Scinto
Christina Schwarz, Fitzpatrick, Cella, Harper & Scinto
Speakers: Claire M. Vasios, Ph.D., Vice President, Alkermes, Inc.
Peter J. Waibel, Esq., Executive Director – Patent Litigation, Novartis
Dr. Aliki Nichogiannopoulou, EPO

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