



IP & Diagnostics Symposium

September 26, 2014 | Hilton Alexandria Old Town

Event Overview

BIO's IP & Diagnostics Symposium (BIO IPDX) will review the current patent law landscape and evaluate the impact on both the genetic diagnostics and biopharmaceutical sectors. The program will review IP issues for both diagnostics generally and companion diagnostics. The program will also explore some of the potential regulatory dimensions. BIO aims to use this event to inform industry and government alike on how to move the science forward in the current climate.

Who Should Attend?

This event is primarily geared towards patent practitioners in the life sciences, both in-house and in private practice. In-house regulatory affairs staff, licensing professionals, business development executives and regulatory agency staff seeking to understand the special premarketing and intellectual property challenges in this area would likewise benefit.

Where & When

Friday, September 26, 2014

Hilton Alexandria Old Town Hotel | 1767 King Street, Alexandria, VA 22314

Registration

Although there is no fee to register, space is limited and you must reserve your seat. To promote a diverse audience, BIO asks that each company/organization register no more than two (2) people. Exceptions will be made for government attendees. To register, please contact Caroline Arrington at carrington@bio.org or (202) 962-9228.

Schedule of Events

*subject to change

Session 1: Squaring the Circle: Obtaining Patents That Are Valid, Commercially Meaningful, and Enforceable

8:15 – 9:30 am

Sponsored by: McDonnell Boehnen Hulbert & Berghoff LLP

The panel will discuss strategies for obtaining patent protection for natural product drugs and diagnostic methods, in view of recent Supreme Court cases and how those cases are interpreted by lower courts and the PTO. Specifically, the panelists will discuss the PTO Guidances interpreting the *Mayo* and *Myriad* cases, and the consequences that will result depending on how broadly this precedent is applied.

Moderator: Don Zuhn, Partner, McDonnell Boehnen Hulbert & Berghoff LLP

Panelists:

Sherry Knowles, Principal, Knowles IP Strategies

Kevin Noonan, Partner, McDonnell Boehnen Hulbert & Berghoff LLP

Session 2: Recent Patent Litigation & Disputes

9:30 – 10:45 am

Sponsored by: Brinks Gilson & Lione

The Supreme Court decisions in *Myriad* and *Prometheus* have significantly impacted the biotech industry and the consequences are not yet fully known. The panel will discuss ongoing cases and recent decisions from the trial courts, the CAFC and the Supreme Court such as *In re Roslin Institute*; *Ariosa Diagnostics v. Sequenom*; *Myriad Genetics v. Quest*, *Gene by Gene*, *Invitae*, *Labcorp*, *Counsyl*, *Ambry Genetics*, and *GeneDx*; *Celltrion Healthcare Co. et al. v. Janssen Biotech, Inc.* and *Kennedy Trust for Rheumatology Research*; *St. Jude Children's Research Hospital, Inc. v. Amgen Inc.*; and more.

Moderator: Jennifer Fox, Counsel, Brinks Gilson & Lione

Panelist:

Andrew Shyjan, Corporate Counsel, MedImmune

Networking Break

10:45 – 11:00 am

Session 3: Is there a New Frontier in University/Industry and Industry/Industry Collaborations?

11:00 am – 12:15 pm

Sponsored by: Schwegman, Lundberg & Woessner, P.A.

The panel will discuss the impact of recent case law on commercialization efforts, new license agreements and collaborations, and the incidence of license termination, particularly with regard to direct-to-consumer tests, personalized medicine and/or companion diagnostics. The panel will also discuss strategies on how to structure deals in view of the “new normal”.

Moderator: Warren Woessner, Attorney & Founding Shareholder, Schwegman, Lundberg & Woessner, P.A.

Panelists:

Leslie Fischer, Sr. Patent Attorney, Novartis Pharmaceuticals Corporation

Rodney Sparks, Sr. Biotechnology Patent Counsel, University of Virginia Licensing & Ventures Group

David Hoffman, Sr. Corporate Counsel, IP & Transactions, Genomic Health, Inc.

Working Luncheon & Session 4: Potential Impacts of Regulatory Changes

12:15 – 2:00 pm

Sponsored by: Morgan, Lewis & Bockius LLP

This panel will focus on the politicized regulatory environment for laboratory developed tests (LDTs). The panel will discuss FDA’s attempt to move from a policy of enforcement discretion to a more regulated environment and the impact on direct-to-consumer tests, personalized medicine and companion diagnostics.

Moderator: Phoebe Mounts, Partner, Morgan, Lewis & Bockius, LLP

Panelist:

Scott McGoohan, Vice President, Reimbursement & Scientific Affairs, American Clinical Laboratory Association

Alberto Gutierrez, Director of the Office of In Vitro Diagnostics and Radiological Health, Food & Drug Administration

Closing Remarks

2:00 – 2:30 pm



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REGISTRATION FORM

Registrant Information:

Prefix First Name Middle Initial Last Name

Title

Company

Address

City State Zip

Email Address of Registrant Phone Number

Please fill in all of the information fields above. Completed registration forms may be submitted via email attachment to carrington@bio.org or faxed to BIO's Legal & IP Department at (202) 488-0650. Once the registration form is received and processed, the registrant will receive a confirmation email.

Questions? Please contact Caroline Arrington at carrington@bio.org.