2016 BIO IP & Diagnostics Symposium
Thursday, September 29, 2016
Program Outline as of 8/15/2016

Registration
8:00 am – 2:00 pm

Breakfast
7:45 am – 8:15 am

Session 1: Diagnostic Tests – Is There Anything Left to Patent?
8:15 am – 9:30 am
Sponsored by: Schwegman Lundberg & Woessner, P.A.

This panel will focus on the case law and PTO Guidance post-*Ariosa*, including opinions from the Federal Circuit and the lower courts that may begin to reveal a path out of the legal "House of Sand and Fog" that has enveloped the requirements of section 101.

Panelists:
Moderator, Warren Woessner, Schwegman, Lundberg & Woessner, P.A.
Leslie Fischer, Novartis
Hans Sauer, Biotechnology Innovation Organization

Session 2: Patenting Diagnostics and Personalized Medicine in Europe and Beyond
9:30 am – 10:45 am
Sponsored by: European Patent Office

The panel will provide an overview on patentability requirements for diagnostics and personalized medicine in Europe and give some hints on procedures and claim drafting. As patenting of diagnostics becomes increasingly difficult in the US, the panel will also ask whether EP patents could provide a safe harbor for applicants in this field. Finally, the implications of the apparent split of European and US practice for users of the system and society at large will be discussed.

Panelists:
Moderator, Berthold Rutz, EPO
Jennifer Enmon, European Patent Attorney, Registered US Patent Attorney, Vossius & Partner
Arti Rai, Elvin R. Latty Professor of Law and co-Director, Duke Law Center for Innovation Policy, Duke University

Networking Break **10:45 am - 11:00 am**

Session 3: How Diagnostics can be Developed in a Post-*Mayo* World
11:00 am – 12:15 pm
Sponsored by: McDonnell Boehnen Hulbert & Berghoff LLP

The patenting landscape surrounding diagnostic methods has been thrown into disarray by several U.S. Supreme Court decisions over the past five years. One of the predicted consequences of the current patent situation is that it is inimical to investment, because the uncertainty caused by the Supreme Court makes it much more likely that the patents providing exclusivity on a diagnostic method claim can be invalidated by an infringer. Indeed, that is exactly what happened to Sequenom on its prenatal diagnostics blood test, and the Court refused to reconsider its precedent even in the face of evidence the infringer intentionally used the law to be able to take advantage of the investment Sequenom had made in developing the technology. This panel will discuss the present and potentially long-term effects of this situation on the development of diagnostic methods in the U.S.

Panelists:
Moderator, Don Zuhn, McDonnell Boehnen Hulbert & Berghoff LLP
Kevin Noonan, McDonnell Boehnen Hulbert & Berghoff LLP

Working Lunch & Session 4: Regulation of Diagnostics: Trends and Developments
12:15 pm – 2:00 pm
Sponsored by: Covington

Panelists will provide an overview and update on the regulatory environment for diagnostic tests. The panel will discuss FDA's role in regulating LDTs, FDA's recent guidance documents on NGS-based tests and codevelopment of companion diagnostics, and current legislative efforts that could impact the regulation of diagnostics.

Panelists:
Moderator, Scott Danzis, Covington & Burling LLP
Wade Ackerman, Covington & Burling LLP

Closing Remarks

2:00 pm - 2:30 pm