PROGRAM

Keynote Breakfast  
Jeffrey N. Peterson, Chief Executive Officer, Target Discovery, Inc.  
8:00 am – 9:30 am

Session One: Obtaining Patent Protection  
Sponsored by: McDonnell Boehnen Hulbert & Berghoff LLP  
9:30 am – 11:00 am

The first panel will discuss strategies for obtaining patent protection for diagnostic reagents and methods in light of recent decisions from the Supreme Court and Federal Circuit. The panel will provide views from in-house patent counsel, outside counsel and a representative from the US Patent and Trademark Office.

Moderator: Don Zuhn, McDonnell Boehnen Hulbert & Berghoff LLP  
Panelists:  
Kevin Noonan, McDonnell Boehnen Hulbert & Berghoff LLP  
Duane Marks, Patent Counsel, Roche Diagnostics Operations, Inc.  
Mary Till, Legal Advisor, Office of Patent Legal Administration, U.S. Patent & Trademark Office

Networking Break  
11:00 am – 11:15 am

Session Two: Regulatory & Reimbursement  
Sponsored by: Brinks Hofer Gilson & Lione  
11:15 am – 12:30 pm

This panel will present an overview of the FDA review process for investigational drugs being developed with companion diagnostics, and tips for regulatory submissions specialists in preparing pre-IND packages, participating in meetings with the FDA, and preparing IND and NDA filings. The panel will also address reimbursement strategies and potential issues for companies developing diagnostics. Special emphasis will be placed on information that will help patent practitioners and licensing professionals integrate IP considerations into broader development and commercialization plans.

Moderator: Jennifer L. Fox, Counsel, Brinks Hofer Gilson & Lione  
Panelists:  
Sheila D. Walcoff, Founding Principal, Goldbug Strategies LLC  
Jeffrey N. Gibbs, Hyman, Phelps & McNamara, P.C.

Working Luncheon & Session Three:  
Business Development & Strategic Deals  
Sponsored by: Sterne Kessler Goldstein & Fox LLP  
12:30 pm – 2:15 pm
The panel will discuss best practices in structuring commercial collaborations and transactions in the personalized medicine and companion diagnostics space and the impact of recent case law on patents in this industry.

*Moderator:* Eric Steffe, Director, Sterne Kessler Goldstein & Fox LLP  
*Panelists:*  
  - Timothy Shea, Jr., Director, Sterne Kessler Goldstein & Fox LLP  
  - Pia Maria Gargiulo, PhD, Managing Director, Companion Diagnostics, Precision for Medicine  
  - Mollie Roth, Managing Partner, PGx Consulting  
  - Zoran Zdraveski, Senior Director of Intellectual Property, Epizyme, Inc.

**Closing Remarks**  
2:15 pm – 2:45 pm