FTC RO

10:30 - 10:45 Morning Break

10:45 - 12:00 Likely Competitive Effects of Reference Product Regulatory Exclusivity

Moderators: Michael Wroblewski, Attorney, FTC, Bureau of Competition, Office of Policy and Coordination, and Christopher Garmon, FTC, Bureau of Economics

10:45 - 10:55 Background Presentation: Linda Horton, Hogan & Hartson, "The European Experience with Follow-On Biologic Legislation"

10:55 - 12:00 Participant Discussion

Discussion Topics: The participants will discuss the economic model to assess the pros and cons of any regulatory exclusivity period provided to referenced products from both the innovator firms' and FOB applicants' perspectives. In particular, panelists will discuss issues of recoupment and innovation in relation to the time periods preventing FOB competitors from seeking regulatory approval. Panelists also will explore the pros and cons of varying the length of any regulatory exclusivity period based on whether an FOB entrant is a biogeneric or biosimilar product and other ways to encourage innovation.

Roundtable Participants:

- Alexis Ahlstrom, MPH, Director, Avalere Health LLC
- Geoffrey Allan, PhD, President and CEO, Insmed Inc
- Alex M. Brill, Research Fellow, American Enterprise Institute
- Linda Horton, Partner, Hogan & Hartson
- David Golding, R.Ph, Executive Vice President for Specialty Pharmacy Services, CVS Caremark
- Henry C. Grabowski, PhD, Professor, Duke University
- Paul Heldman, Senior Health Policy Analyst, Potomac Research
- Audrey Phillips, PhD, Executive Director of Biopharmaceutical Public Policy and Advocacy, Johnson & Johnson
- Mateja Urlep, R.Ph, MS, Head Global Ma

Roundtable Participants

- Geoffrey Allan, PhD, President and CEO, Insmed, Inc.
- Aaron Barkoff, PhD, Partner, McDonnell Boehnen Hulbert & Berghoff LLP
- Marc A. Goshko, MS, Executive Director Legal Affairs, TEVA Pharmaceuticals, North America
- Steven B. Miller, MD, MBA, Senior Vice President and Chief Medical Officer Express Scripts, Inc.
- Doug Norman, General Patent Counsel, Eli Lilly and Company
- William B. Schultz, Partner, Zuckerman Spaeder LLP
- Bryan Zielinski, MS, Assistant General Counsel, Intellectual Property, Pfizer

2:50 - 3:00 Afternoon Break

3:00 - 5:00: Patent Dispute Resolution Processes

Moderators: Michael Wroblewski and Suzanne Drennon, Attorneys, FTC, Bureau of Competition, Office of Policy and Coordination

3:00 - 3:15 Presentation of Biotechnology Patent Portfolio Case Study: Rochelle Seide, Senior Counsel, Schwegman, Lundberg & Woessner

3:15 - 5:00 Participant Discussion

Discussion Topics: The participants will discuss the need for, and the likely competitive effects of, different ways to structure a process to resolve patent disputes between innovator firms and FOB applicants prior to FDA approval of FOB products. The participants will use the Case Study to focus on: (1) when to start such a process; (2) how and to whom such notifications will be provided; and (3) what patents to be included in such a process (including patents obtained after such a process has begun).

Roundtable Participants

- Elaine Blais, Partner, Goodwin Proctor LLP, outside patent counsel to TEVA Pharmaceuticals, North America
- Ken Dow, Assistant Patent Counsel, Johnson & Johnson
- Ken Goldman, MS, Vice President Intellectual Property Strategy, Novartis International AG
- Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, Inc.
- Esther Kepplinger, Director, Patent Operations, Wilson Sonsini Goodrich & Rosati
- Jeffrey P. Kushan, Partner, Sidley Austin LLP
- David Manspeizer, VP Intellectual Property & Associate General Counsel, Wyeth
- Hans Sauer, MS, PhD,Associate General Counsel, Intellectual Property, BIO
- Rochelle Seide, Senior Counsel, Schwegman, Lundberg & Woessner
- William B. Schultz, Partner, Zuckerman Spaeder LLP
- Christine J. Siwik, Partner, Rakoczy Molino Mazzochi Siwik LLP