FTC ROUNDTABLE ON
FOLLOW-ON BIOLOGIC DRUGS:
FRAMEWORK FOR COMPETITION AND CONTINUED INNOVATION

November 21, 2008
Federal Trade Commission
600 Pennsylvania Avenue, N.W., Room HQ 432
Washington, D.C. 20580

8:30 - 8:45 **Welcoming Remarks: FTC Commissioner Pamela Jones Harbour,**

8:45 - 9:00 **Opening Remarks: Rachel Behrman, FDA, "How Do Biologic Drugs Differ from Small Molecule Drugs?"**

9:00 - 10:30 **Likely Market Effects of Follow-On Biologic (FOB) Drug Competition**

Moderators: Michael Wroblewski and Elizabeth Jex, Attorneys, FTC, Bureau of Competition, Office of Policy and Coordination and Mergers I

9:05 - 9:20 **Background Presentation: Paul Heldman, Senior Health Policy Analyst, Potomac Research, "Overview of Biologic Drug Markets"**

9:20 - 10:30 **Participant Discussion**

Discussion Topics: Participants will discuss the likely price and market share effects of entry by biosimilar and potential biogeneric (*i.e.*, substitutable and interchangeable with the referenced product) drug products. They also will discuss the likely competitive effects Follow-on Biologic (FOB) drug products will have on reimbursement by private and public (*e.g.*, Medicare Part B) payers.

Roundtable Participants:

- Alexis Ahlstrom, MPH, Director, Avalere Health LLC
- Rachel E. Behrman, MD, MPH, Director, Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration
- Steven B. Brugger, MBA, Chief Operating Officer, Momenta Pharmaceuticals, Inc.
- Ted Buckley, PhD, Director, Economic Policy, Biotechnology Industry Organization
- 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
- John Lane, MBA, Vice President, Biologics, Hospira, Inc.
- Mateja Urlep, R.Ph, MS, Head Global Marketing & Medical, Biopharmaceuticals, Sandoz International

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 Marketing & Medical, Biopharmaceuticals, Sandoz International

12:00-1:00 Lunch Break

1:00-2:00 Biotechnology Patent Issues

Moderators: Suzanne Michel, Assistant Director, FTC Bureau of Competition, Office of Policy and Coordination, and Suzanne Drennon, Attorney, FTC Bureau of Competition, Office of Policy and Coordination

1:00 - 2:00 Participant Discussion
Discussion Topics: The participants will discuss the interaction between patents claiming biotechnology products and regulatory exclusivity periods. The panelists will discuss whether there are differences between biotechnology patents and small molecule patents relating to (1) claim drafting and PTO approval processes; and (2) trends regarding judicial review. They also will discuss whether regulatory exclusivity and patent rights affect innovator firm and FOB applicant needs for business planning certainty.

Roundtable Participants
- Ken Dow, Assistant Patent Counsel, Johnson & Johnson
- Ken Goldman, MS, Vice President, Intellectual Property Strategy, Novartis International AG
- Esther Kepplinger, Director, Patent Operations, Wilson Sonsini Goodrich & Rosati
- Jeffrey P. Kushan, Partner, Sidley Austin LLP
- Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, Inc.
- David Manspeizer, VP Intellectual Property & Associate General Counsel, Wyeth
- Doug Norman, General Patent Counsel, Eli Lilly and Company
- Naomi Pearce, IP Director and Counsel, Hospira, Inc.
- Rochelle Seide, Senior Counsel, Schwegman, Lundberg & Woessner

2:00-2:05: Break

2:05 - 2:50: Likely Competitive Effects of Follow-on Biologic Regulatory Incentives

Moderators: Michael Wroblewski and Elizabeth Jex, Attorneys, FTC, Bureau of Competition, Office of Policy and Coordination and Mergers I

2:05 - 2:50: Participant Discussion
Discussion Topics: Participants will discuss whether there is a need to provide regulatory incentives for the filing of FOB applications. The participants will examine the effects of using a marketing exclusivity period for FOB products similar to the one provided generic applicants under the Hatch-Waxman Act. They also will discuss whether such incentives are necessary to encourage the development of biogeneric FOB products.

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