5th Annual In-House Counsel Forum on

PHARMACEUTICAL ANTITRUST

Understanding Antitrust Priorities Under a New Enforcement Regime

Gain firsthand insights from leading in-house pharmaceutical counsel, government regulators, and expert attorneys on how to successfully tackle the most complex antitrust issues currently facing brand name and generic pharmaceutical manufacturers:

- Reverse settlement payment agreements
- Mergers & acquisitions
- Life cycle management, including product migration, authorized generics and citizens petitions
- Follow-on biologics
- Pricing, distribution and related Robinson-Patman issues

Hear from key government agencies directly involved in pharmaceutical antitrust enforcement:

**Federal Trade Commission:**
- Commissioner J. Thomas Rosch
- Michael B. Kades
  Attorney Advisor to Chairman Jon Leibowitz

**Bureau of Competition:**
- Richard Feinstein
  Director
- Markus Meier
  Assistant Director, Health Care Division
- Michael Moiseyev
  Assistant Director, Mergers I Division
- Michael Wroblewski
  Deputy Assistant Director, Policy Division

**USDOJ, Antitrust Division**
- Philip Weiser
  Deputy Assistant Attorney General

**European Commission, DG Competition, Pharmaceuticals Task Force** – Harald Mische

NY Attorney General’s Office, Antitrust Bureau – Elinor Hoffman (Invited)

FL Attorney General’s Office, Antitrust Division – Elizabeth Arthur (Invited)

Hear Directly From:

- Pfizer & Wyeth during a special panel on Pharmaceutical Mergers

As well in-house insights from:

- Bristol-Meyers Squibb
- Eli Lilly and Company
- European Federation of Pharmaceutical Associations

Distinguished Co-Chairs:

- Jeffrey W. Brennan
  Dechert LLP
- Seth Silber
  Wilson Sonsini Goodrich & Rosati

Master Class – February 19, 2010

Managing All Phases of FTC Pharmaceutical Antitrust Investigations and Litigation

Sponsored By:

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Now is the time to evaluate how pharmaceutical antitrust enforcement, both in the U.S. and abroad, will impact your business over the next year.

The principal area of concern for pharmaceutical drug manufacturers right now is increased government enforcement stemming from reverse settlement payment agreements, pricing and distribution tactics, life cycle management, as well as strategic responses by both brand name and generic manufacturers to competitive challenges within the industry. Recent high-profile pharmaceutical mergers combined with increased pressure from Capitol Hill to create a regulatory pathway for follow-on biologics, necessitates that drug manufacturers remain abreast of how emerging enforcement trends will ultimately impact antitrust analysis undertaken by the government when evaluating industry behavior in the future.

There is now heightened cooperation between the FTC and the DOJ on matters of pharmaceutical antitrust enforcement, while the circuits still differ on the legality of reverse settlement payment agreements.

Conflict among the Circuits regarding whether or not reverse settlement payment agreements are per se illegal combined with a closer alignment between the FTC and the USDOJ Antitrust Division, have in-house counsel wondering – what will come next? How are these agencies going to execute their enforcement plan on the industry?

Adding another layer of complexity to antitrust enforcement environment in the U.S., the European Commission, in July 2009, released its long awaited final Pharmaceutical Sector Inquiry Report, finding that generic entry within the European pharmaceutical market has in fact been delayed and promising future investigation into the industry, some of which are already underway.

Never before has there been such a convergence by antitrust authorities on both sides of the Atlantic.

Featuring a faculty comprised of the leading authorities on antitrust enforcement within the pharmaceutical industry, take advantage of this rare opportunity to hear directly from the FTC’s Bureau of Competition, Healthcare, Policy & Mergers I Divisions, as well as the USDOJ Antitrust Division, the European Commission and the Florida and New York State Attorneys General Offices.

Also hear directly from the Honorable Gerald Tjoflat of the U.S. Court of Appeals for the 11th Circuit and Paul Clement, Former Solicitor General of the U.S., as they provide commentary and insights into recent cases that have addressed reverse settlement payments.

Reserve your space now at what is sure to be a sold-out event by calling 888-224-2480, faxing your registration to 877-927-1563, or registering online at www.AmericanConference.com/PharmaAntitrust.

Register now: 888-224-2480 • fax: 877-927-1563 • AmericanConference.com/PharmaAntitrust
With new leadership at the helm at both the FTC and DOJ Antitrust Division, it is clear that a closer alignment is being forged between the two agencies. The DOJ has assumed a new position on enforcement under Section 2 of the Sherman Act, while continued activity by the FTC leaves many in the industry trying to determine how actions taken by the two agencies will impact the pharmaceutical industry as a whole.

During this session, hear directly from the current and former Assistant Director of the FTC’s Health Care Division as they provide you with an overview of what the Division’s pharmaceutical antitrust enforcement priorities are. Providing you with specific insights into what you can expect in the near future by way of FTC enforcement in this area, topics of discussion will include:

- How has the Commission has adjusted its enforcement prerogatives or modified its competitive analysis of pharmaceutical sector conduct due to changes in the economy or political leadership over the past year?
- Patent settlement agreements have been an FTC priority for about a decade. What has staff learned over that time? Has experience affected how staff investigates settlement agreements? Has private antitrust counseling had to change over this period?
- You filed your settlement agreement with the Agencies; what happens next?
  - Insights into FTC processes: When is the settlement reviewed? How long does the review take? What is staff looking for? Will staff want more information?
  - Perspectives on effective counseling strategies before and after you file your settlement. Should counsel initiate discussion with staff or “lay low” unless/until staff calls?

It is important to note that a sector inquiry ‘bears fruit’ over a number of years … So please look out for further news in the coming months.”

– Neelie Kroes
Commissioner for Competition
European Commission, September 2009
At press time, the status of several key bills affecting the pharmaceutical industry is still unknown. The outcome of these and other pending legislative matters could cause shockwaves throughout the pharmaceutical industry. The speakers will provide strategic guidance on how to prepare for potential changes in the status of the law concerning:

- **Reverse settlement payments – Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706), Preserve Access to Affordable Generics Act (S. 369)** which would restrict brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market
- **Follow-on biologics – Promoting Innovation and Access to Life-Savings Medicine Act of 2009 (H.R. 1427; S. 729)** which would create a regulatory pathway for the approval of biologic products as well as outline what the applicable period of market exclusivity will be for biologic products
  - considering the impact of various market exclusivity periods on competition within the market (5/7/14 years exclusivity)
  - will biologic products qualify for use under state substitution laws?
  - potential impacts on pricing?
- **Authorized Generics – A bill to amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs (H.R. 573; S. 501)**

2:45  **Avoiding the Appearance of “Predatory Pricing” by Carefully Crafting Pricing and Distribution Strategies That Are In Line with Robinson-Patman**

**Moderator:**

Seth Silber  
Of Counsel  
Wilson Sonsini Goodrich & Rosati (Washington, DC)

Robert P. Reznick  
Co-Chair, Pharmaceuticals and Healthcare Industry Practice Group  
Chair, Antitrust Practice Group, Washington, DC Office  
Hughes Hubbard & Reed LLP  
(Washington, DC)

Stephen J. Cipolla  
Counsel  
Merck & Co., Inc. (North Wales, PA)

**Keynote Address: Focus on Reverse Settlements Payment Agreements, Authorized Generics and Pharmaceutical Mergers**

The Honorable J. Thomas Rosch  
Commissioner  
Federal Trade Commission (Washington, DC)

9:30  **Morning Refreshment Break**

9:45  **Life Cycle Management: Perspectives from State Attorneys General on Current Enforcement and Strategies for Expanding Product Life While Also Minimizing Exposure to Antitrust Scrutiny**

Recent high-profile mergers within the pharmaceutical industry have cast a new light on how the industry is tackling the inherent challenges presented by the expiration of key blockbuster patents in coming years. In this increasingly competitive market, companies both large and small are beginning to take strategic steps towards maintaining (and even expanding) their current position within a given treatment area.

During this session, gain firsthand insights into how state Attorneys General have been prosecuting cases arising out of life cycle management issues, as well as insights into the use of product migration tactics, authorized generics, and citizens petitions.

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Spotlight Address: (9:45-10:15)

TriCor – A Case Study

Elizabeth G. Arthur (Invited)
Assistant Attorney General, Antitrust Division
Office of the Attorney General of the State of Florida (Tallahassee, FL)

Panel: (10:15-11:00)

David L. Meyer
Co-Chair of the Global Antitrust and Competition Law Practice Group
Morrison & Foerster LLP (Washington, DC)
 Former Principal Deputy Assistant Attorney General, Antitrust Division, USDOJ

Michael S. McFalls
Partner
Jones Day (Washington, DC)

Product Migration

- Conducting an antitrust analysis of various product migration strategies to extend product life
  - line extensions
  - special issues surrounding “me-too” products
  - revisiting dosage form
- Understanding what litigation risks are presented by various product migration strategies – and what you can do to minimize your exposure to them

Authorized Generics

- FTC Interim Report on “Authorized Generic” Drugs – understanding the implications of the report’s findings on drug competition between brand name and generic manufacturers
  - balancing competing interests – weighing the benefit of allowing authorized generics prior to the expiration of the brand name patent vs. the incentives of first ANDA filers to pursue generic entry prior to patent expiration
  - addressing the FTC’s current position on brand-generic agreements which delay the introduction of both authorized generics and independent generics

Citizens Petitions & Other Forms of Regulatory Practice

- Antitrust analysis regarding citizen petitions
- Determining when petitioning conduct is/is not immune from attack under Noerr-Pennington
- Lessons from recent private actions challenging citizen petitions as sham

11:00 Minimizing Exposure to Liability by Preemptively Analyzing the Antitrust Implications of Engaging in Collaborative Activities

Thomas O. Barnett
Co-Chair, Antitrust & Consumer Law Practice Group
Covington & Burling LLP (Washington, DC)
 Former Assistant Attorney General, Antitrust Division, USDOJ

Melissa S. Barnes
Assistant General Counsel
Eli Lilly and Company (Indianapolis, IN)

In-licensing and co-development

- Understanding what types of restrictions/limitations can be imposed on a licensee without triggering antitrust scrutiny
  - revisiting dosage form
  - special issues surrounding “me-too” products

12:00 Networking Lunch


Plaintiff’s Perspective:
Linda P. Nussbaum
Partner, Kaplan Fox & Kilsheimer LLP (New York, NY)

Defense Perspective:
Sean Gates
Partner, Morrison & Foerster LLP (Los Angeles, CA)

Moderator:
Jonathan Wasserman
Vice President & Senior Counsel
Bristol-Myers Squibb (Plainsboro, NJ)

- Anticipating issues that may arise with potential competition and innovation during the diligence review process
  - considering how Quanta and developing case law on patent exhaustion will impact antitrust analyses conducted during pharmaceutical transactions
- Handling exclusive in-licenses
- Screening and distributing antitrust-sensitive royalty payments
- Drafting non-compete provisions that will withstand government scrutiny
- Strategies for fulfilling government notification requirements (Hart-Scott-Rodino)
- Handling unique issues that arise in the context of joint ventures – calculating product assessments that both parties will agree with

Co-promotion and co-marketing

- Ensuring the arrangement avoids credible charges of market division or price fixing
- Drafting exclusivity and non-compete provisions that will withstand government scrutiny

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Despite a turbulent financial climate, this year has seen the return of or DOJ. re-examine their merger to assess the risk of later challenges by the FTC already consummated merger that fell below the Hart-Scott-Rodino threshold, new issues are being exposed that may cause companies to changed under the new administration, and if so, what the new insight into whether the FTC's approach to evaluating mergers has high-profile mergers within the pharmaceutical industry, providing an understanding of the Commission's highest priorities. “No matter what you call them, eliminating these deals is one of the Federal Trade Commission’s highest priorities.” – Jon Leibowitz Chairman, Federal Trade Commission, June 23, 2009

Government Panel: (4:00 – 4:40)

Analysis of the USDOJ’s Position in In re Cipro
Philip Weiser Deputy Assistant Attorney General, Antitrust Division U.S. Department of Justice (Washington, DC)

Current FTC View on Pay-for-Delay Settlements
Michael B. Kades Attorney Advisor to Chairman Jon Leibowitz Federal Trade Commission (Washington, DC)

Industry Panel: (4:40 – 5:30)

Structuring Settlement Agreements that Won’t Raise Antitrust Concerns
Lauren Freeman-Bosworth Legal Director, Schering-Plough Corporation (Kenilworth, NJ)
Donald L. Flexner Managing Partner, Boies, Schiller & Flexner LLP (New York, NY)

Over the past few years, “reverse settlement” or “pay-for-delay” agreements have come to be an increasingly contentious point of debate within the pharmaceutical industry. The FTC, and now the DOJ, both hold the position that these agreements are anti-competitive, while the Courts have taken varying approaches to this issue. Additionally, although the FTC has been steadily pursuing litigation that would bring a final resolution to this issue, the U.S. Supreme Court, for the third time, in In re Ciprofloxacin Hydrochloride Antitrust Litigation, declined to grant certiorari on yet another case where the legality of reverse settlement payments was at issue. Adding another layer of complexity to this issue, is legislation pending in Congress which would prohibit reverse settlement payments all together. With the law on this issue in such a state of flux, companies must tread carefully when considering the options for structuring settlements as part of Hatch-Waxman litigation.

During this session, learn how to structure settlement agreements that will pass antitrust scrutiny, as well as what steps you can take now to prepare for changes in the law that may take place over the next year.

Topics of discussion will include:
- Identifying what factors to consider when crafting a Hatch-Waxman settlement
  - will a limited term or delayed license be granted?
  - understanding the impact of the following on settlement –
    - 180-day exclusivity for later infringers
    - forfeiture provisions under the MMA
  - considering the amount of the payment/consideration being given to the generic company
- Complying with the MMA filing requirements
  - understanding how “side deals” with patent settlements are being reviewed by the FTC
  - how to apply the varying standards among the circuits to your proposed settlement agreement
- Considering the impact a change in position by the 2nd Circuit could have on the Supreme Court’s willingness to accept a case

Panel: (3:00-4:00)

Aryeh Friedman
Chief Counsel, Antitrust
Wyeth (Collegeville, PA)

Marc Brotman
Assistant General Counsel
Pfizer Inc (New York, NY)

- Understanding how the Hart-Scott-Rodino process is applied to pharmaceutical mergers
- Incorporating a comprehensive due diligence analysis into your assessment of the deal to uncover potential antitrust issues
- Recognizing how changes within the pharmaceutical development pipeline have impacted companies’ motivations for pursuing mergers
  - expansion within a particular treatment vs. expansion based on general innovation
- Determining what substantive analysis is being applied to evaluate pharmaceutical mergers (both horizontal and vertical), as well as analysis of potential competition between and among industries
  - brand-brand
  - brand-generic
  - generic-generic
  - with biotechnology companies
  - divestiture of product lines
  - being aware of various red flags that may trigger downstream FTC/DOJ interest in your deal although premerger notification was not required under Hart-Scott-Rodino
- Knowing the FTC’s approach to remedies –
  - relationship to substantive violation
  - procedural pitfalls


– Jon Leibowitz
Chairman, Federal Trade Commission, March 2009

Panel: (3:00-4:00)

Michael R. Moiseyev
Assistant Directors, Mergers I, Bureau of Competition
Federal Trade Commission (Washington, DC)

Spotlight Address: (2:30-3:00)

– Jon Leibowitz
Chairman, Federal Trade Commission, March 2009

“Even in “down markets,” the Commission must hold the line against industry consolidation that may threaten competitive markets far into the future.”

Pharmaceutical Mergers and Acquisitions: Lessons Learned from Recent High-Profile Activity and Best Practices Going Forward

Michael R. Moiseyev
Assistant Directors, Mergers I, Bureau of Competition
Federal Trade Commission (Washington, DC)

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Federal T rade Commission (Washington, DC)
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WHO YOU WILL MEET

- In-House counsel at brand name and generic pharmaceutical companies
- Outside counsel to pharmaceutical companies:
  - Antitrust attorneys
  - Litigation attorneys
  - Patent/IP attorneys
- Business Development and licensing executives at brand name and generic pharmaceutical companies

Litigation
- Understanding the FTC review process and the convergence between standards used by the FTC and various agencies when pursuing litigation
- Mastering pre-litigation due diligence
- Deciding whether to file an antitrust claim
- Determining initial defense strategies to an antitrust claim
- Evaluating possible remedies, including injunctive relief
- Considering whether to pursue an antitrust counterclaim as part of infringement litigation
- Once Paragraph IV certification has been served, knowing what is involved in filing an antitrust counterclaim in response to an infringement action
- Informing the company’s board, management, and employees of litigation (from the plaintiff’s and defendant’s perspective)
- Selecting and working with counsel and experts, including economists
- Working with management, internal staffing, and setting up reserves
- Gathering documents and electronic records in the pre-trial period
- Managing discovery and best document preservation practices
- Assessing the role of the attorney-client privilege
- Determining whether and when to file dispositive motions, including summary judgment
- Defending against dispositive motions
- Using the “advice of counsel” defense, and other antitrust-specific defenses including standing and antitrust injury
- What happens after the case is over?

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**Registration Form**

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