

WHO SHOULD ATTEND:

- Attorneys
- Corporate counsel
- Industry analysts

BNA Presents a One-Day Briefing on:

PHARMACEUTICAL PATENT LAWS: A Prescription for Success in Challenging Times

November 12, 2008
Ritz-Carlton Pentagon City
Arlington, VA

A fast-paced conference on the latest developments and changes in pharmaceutical patent law—get insights from key government regulators, industry insiders, and leading legal experts.

- Patent litigation and settlement strategies
- Product life cycle management
- What to expect from the next Congress

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BNA, the leading provider of expert information and analysis, invites you to this one-day, information-packed conference. Get a prescription for success as legislative, judicial, administrative, and ‘marketplace’ developments continue to advance at breakneck speed—this conference will help you:

- Get maximum value from your patents.
- Learn winning litigation tactics from leading practitioners.
- Avoid antitrust consequences when settling cases.
- Look for trends—where does case law go from here?

Recent case law developments, the 2003 Medicare Modernization Act, and even the 2007 FDA Amendments Act have changed the landscape for drug companies defending or challenging patents. As brand-name companies strive to maximize the market exclusivity for their products, generic drug makers try to enter the market before patents expire. Your clients will need advice on the nuts and bolts of managing product life cycles. How do they position their products for the best possible market share?

This program will present strategies for generic companies on how to challenge patents. In past years, generic companies had been losing the battle to secure court jurisdiction through declaratory judgment

actions. However, the Supreme Court decision in the *MedImmune* case and its recent progeny in the Federal Circuit may have changed the prospects of generic companies on standing issues—for good.

Meanwhile, the prospect of Congress making changes to the patent law looms over the entire industry. This conference will keep you current on these crucial issues.

Join BNA and a distinguished faculty of practicing attorneys, outside counsel, and government officials for an exciting, informative, highlight-packed conference. This panel of experts will offer strategies for success to attorneys, corporate counsel, industry analysts, and anyone else who must keep current on pharmaceutical patent law.

ALSO OF INTEREST:

Pharmaceutical Patent Law

By John R. Thomas

This comprehensive treatise is the only reference available with a detailed, practitioner-oriented treatment of pharmaceutical patent law from the perspective of both patent law and the food and drug laws. In scrupulous detail it explains how both food and drug and intellectual property attorneys should coordinate their client's patent filings and FDA strategies.

2005/704 pp. Hardcover
with 2008 Cumulative Supplement
Order #9748/\$385.00

Pharmaceutical Law: Regulations of Research, Development, and Marketing

By Michael E. Clark, Editor-in-Chief
ABA Health Law Section

Get “must have” guidance on issues that could lead to litigation or regulatory problems for your clients. This treatise is the only resource available that provides expert commentary and authoritative insights into a comprehensive range of pharmaceutical law issues. In fact, no other single volume discusses these complex issues in the detail required for transactional health care attorneys to adequately advise their clients on the opportunities—and the liabilities—in this industry.

2007/899 pp. Hardcover
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USING TODAY'S PATENT LAWS TO PROTECT TOMORROW'S TECHNOLOGY: NEW LITIGATION STRATEGIES

PROGRAM HIGHLIGHTS

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. – 9:15 a.m.

Introduction by Program Co-Chairs

Melissa M. Hayworth, Crowell & Moring LLP

Brian R. McCormick, Hogan & Hartson LLP

9:15 a.m. – 9:45 a.m.

Morning Keynote Address

A Key Pharmaceutical Expert Will Provide the Morning Keynote Address

9:45 a.m. – 10:45 a.m.

"Pay for Delay" and Other Continuing Controversies in Pharmaceutical Patent Settlements

J. Mark Gidley, White & Case LLP

Michael B. Kades, United States Federal Trade Commission

H. Keeto Sabharwal, Blank Rome LLP

The Federal Trade Commission, the Department of Justice, state regulators, and private firms continue to scrutinize patent litigation settlements between drug companies—both branded and generic. What does this increased scrutiny mean for your company or client? Which settlements are the latest to raise red flags, and which are becoming standard? Members of the FTC and private attorneys will discuss topics such as:

- The Cephalon-Provigil case
- The latest case law and FTC actions
- The FTC's most recent report on patent settlements
- The potential for the Supreme Court to weigh in on the debate

10:45 a.m. – 11:00 a.m.

Break

11:00 a.m. – 12:00 p.m.

Non-Patent Marketing Exclusivity

Brian R. McCormick, Hogan & Hartson LLP

Stephen R. Albainy-Jenei, Frost Brown Todd LLC

Kurt R. Karst, Hyman, Phelps & McNamara, P.C.

Shashank Upadhye, Apotex, Inc.

In addition to the traditional protection that drug patents provide, the available non-patent marketing exclusivities can be critical for product extensions. They can also protect older drugs with little or no patent life remaining. Get insights from some of the country's leading experts from private practice and in-house counsel, including the authors of the popular blogs PatentBaristas and FDA Law Blog. You'll get answers to the following pressing questions:

- What are the recent controversies surrounding these complex statutory provisions?
- How have FDA's policies on orphan drug designations changed?
- What is the latest in FDA's implementation of the Medicare Act forfeiture provisions?
- How did the 2007 FDA Amendments Act fundamentally change pediatric exclusivity?

12:00 p.m. – 12:45 p.m.

Import and Export Issues

Ralph A. Mittelberger, Arent Fox LLP

Kimberly Orr, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce

Colin G. Sandercock, Proskauer Rose LLP

Whether importation or exportation of an approved pharmaceutical product, intermediate, or compound for testing constitutes actionable infringement under the US Patent Laws or under Section 337 of the ITC can present thorny issues. Drug and biotech companies must know both the laws and the loopholes, as well as how to stop importation of counterfeit and generic drugs using the International Trade Commission. Come hear how the patent laws can be used both as sword and shield. Learn when a Section 337 proceeding before the ITC may provide remedies that are not available in district court. Topics include:

- Permissible and actionable importation/exportation of drugs
- When process patents can be used to stop importation in district courts and the ITC
- Expanded jurisdictional reach and fast-track proceedings using the ITC

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12:45 p.m. – 1:30 p.m.

Luncheon Keynote Address: Two Legislative Currents Driving Biotech Patent Law Reform

Jeffrey P. Kushan, Partner, Sidley Austin LLP

Significant progress was made in the 109th Congress on patent reform and follow-on biologics. The intersection of these two legislative reform efforts will fundamentally reshape patent law and the role patents play for biotechnology therapeutics. Mr. Kushan will provide perspectives on trends he sees with these two reform efforts.

1:30 p.m. – 3:00 p.m.

The Other Kind of Pharmaceutical IP—Regulatory Life Cycle Management Strategies—Opportunities and Challenges

James N. Czaban, Wilmer Cutler Pickering Hale and Dorr LLP

Deborah Shelton, Sheppard Mullin Richter & Hampton LLP

Steven H. Sklar, Leydig, Voit & Mayer Ltd.

Mitchell M. Wong, Morrison & Foerster LLP

Regulatory exclusivities comprise an important part of any drug's overall life cycle management plan, and for some products these offer the only meaningful way of protecting a developing product's market. Learn about leading LCM approaches using data exclusivity, market exclusivity, patent term extensions, pediatric extensions, and patent litigation and settlement strategies, as well as opportunities involving improved formulations, strengths, and dosage forms. This panel will also explore emerging threats to LCM strategies, including antitrust challenges, recent changes in the law of patent "obviousness," proposed legislation to prohibit "authorized generics" and reverse payments in patent settlements, as well as recent controversies regarding patent term restoration, and why the Patent and Trademark Office keeps being sued over the benefit.

3:00 p.m. – 3:45 p.m.

Pharma Post-Election: Predictions for the Future

Michael E. Clark, Hamel Bower & Clark L.L.P.

Professor John "Jay" R. Thomas, Professor of Law Georgetown University Law Center

Listen to the experts debate how the election's aftermath will affect issues important to the pharmaceutical industry, addressing such questions as:

- Will the patent reform bill and generic biologics bills move ahead?
- Will there be more Hatch-Waxman reform?
- How will Medicaid rebate and reimbursement policy be affected?
- Will FTC step up investigations and enforcement efforts in the industry?
- Will 2009 bring a dramatic overhaul in Congressional efforts to "fix" FDA?
- Will the election affect drug prices?

3:45 p.m. – 4:00 p.m. **Break**

4:00 p.m. – 5:15 p.m.

Trends in Declaratory Judgment Actions: Where Are Courts Headed?

Matthew P. Blichak, Sepracor, Inc.

Michael J. Gaertner, Locke Lord Bissell & Liddell LLP

Melissa M. Hayworth, Crowell & Moring LLP

Charles D. Ossola, Dickstein Shapiro LLP

The effect of the Supreme Court's new standing test in *MedImmune* was felt in the Federal Circuit immediately, with the *Novartis* and *Caraco* decisions. What, exactly, is the law with respect to declaratory judgment jurisdiction, and when will Federal Circuit **deny** jurisdiction? Where does the case law go from here? And what, if anything, has been the impact of the 2003 Medicare Modernization Act?

5:15 p.m. – 5:30 p.m.

Closing Remarks

SPONSORING PUBLICATIONS

BNA's *Pharmaceutical Law & Industry Report* and *Pharmaceutical Law & Industry Daily*

Available either weekly or daily, these in-depth *Reports* provide coverage of the wide-ranging developments that affect the pharmaceutical industry, from patent litigation to economic issues to fraud prevention.

- Follow major actions at the federal and state level that focus on intellectual property/patent issues, drug pricing and reimbursement, FDA oversight, and Federal Trade Commission antitrust enforcement.
- Keep current with marketplace news on the forces behind escalating costs and the responses from the public and private sectors.

CO-CHAIRS

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Melissa M. Hayworth
Partner
Crowell & Moring LLP
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KEYNOTE SPEAKERS

MORNING:

A Key Pharmaceutical Expert
Will provide the morning
keynote address

LUNCHEON:

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Member
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CONFERENCE FEES & PAYMENT POLICY:

The registration fee of \$1,295 (special price of \$995 for BNA subscribers) includes the conference, continental breakfast, luncheon, and course materials. Make checks payable to BNA. All payments must be received prior to the start of the conference.

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Cancellations received by 9am ET, seven days prior to the conference, will be accepted, and a full refund will be made, less a \$95 administrative processing fee. Attendee substitutions for this conference may be made at any time. These substitutions are not transferable to other conferences. Seminars are held subject to enrollment. Date, venue, and program details are based on information available upon publication of the brochure, and may be subject to change. In the event of a conference cancellation, BNA will make a full refund of any registration fees paid but assumes no liability for non-refundable transportation costs, hotel accommodations, or additional costs incurred by registrants.

COURSE MATERIALS: In keeping with our commitment to be greener this year, BNA conferences are going "paperless." Registered attendees will be able to access the written materials online before, during, and after the conference. Please note that hard copies of the conference's written materials will not be provided on-site, so be sure to bring your printed copies if you wish to use them to take notes. Power strips will be available for laptop computers. BNA will provide onsite wireless Internet access to all conference attendees. Attendees will receive a certificate of attendance.

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Contact Sara Cribari at scribari@bna.com for more information concerning approval.

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