American Conference Institute's *2nd West Coast Edition*

ACI's HATCH-WAXMAN SERIES

Paragraph IV Disputes

Expert Insights on Hatch-Waxman Litigation Strategies for Brand Names and Generics

December 6 – 7, 2011 • Hotel Nikko • San Francisco, CA

Benefit from an exceptional in-house faculty of counsel to branded and generic companies including:

Avila Therapeutics, Inc.
Baxter Healthcare Corporation
Cubist Pharmaceuticals, Inc.
Eli Lilly and Company
Gilead Sciences, Inc.
Impax Laboratories, Inc.
Medicis Pharmaceutical Corporation
Sandoz Inc.
And many more…

New Features for our West Coast attendees! **A View from the Bench: Formulate your Paragraph IV litigation strategies based on the insights of jurists adept in the intricacies of Hatch-Waxman litigation:**

The Honorable Jeremy Fogel (Invited)
Director, Federal Judicial Center
Former United States District Court Judge
Northern District of California

Honorable Eugene F. Lynch (Retired)
Mediator and Arbitrator, JAMS
Former United States District Court Judge
Northern District of California

Distinguished Co-Chairs:

Madison Jellins
Partner, Alston & Bird LLP (Palo Alto, CA)

Mark E. Waddell
Partner, Loeb & Loeb LLP (New York, NY)

Leading counsel from **branded and generic drug makers, experienced jurists, and the Federal Trade Commission** will provide you with the tools necessary to position your company strategically in light of the latest legal challenges affecting Hatch-Waxman disputes, including:

- **Pinpointing** patents which may be vulnerable to a Paragraph IV challenge
- **Demystifying** an ANDA applicant's **Orange Book** strategy and **dissecting** a challenger's obligations under Paragraph IV
- **Understanding** the FTC's current position on **pay-for-delay** settlements and **anticipating** any antitrust concerns stemming from agreements between brand names and generics
- **Mastering** the intricacies of litigation with **multiple ANDA filers**
- **Weighing** the benefits and risks of an **at-risk launch** and **minimizing** downstream risk
- **Identifying** the legal and ethical impact that ***Therasense*** will have on the affirmative defense of **inequitable conduct**
- **Exploring** the ramifications of increased **generic versus generic** litigation in the quest for the prize of **180-day exclusivity**
- **Navigating** the evolving case law surrounding **double patenting obviousness** and **formulating** litigation strategies based on the **prior art analysis**
- **Scrutinizing** labeling controversies and **determining** whether a **use code** expansion is reasonable

December 7, 2011: Post-Conference Master Class on Settling Paragraph IV Disputes, featuring an **FTC Keynote on Pay-for-Delay Settlements:**
***J. Thomas Rosch*, Commissioner, Federal Trade Commission**

December 5, 2011: Formulate immediate action plans for the reality of long-awaited biosimilars litigation at the **Pre-Conference Boot Camp** on **Biosimilars through the Hatch-Waxman Lens: Anticipating Litigation Challenges and Understanding the Evolving Landscape**

Earn CLE ETHICS Credits

Supporting Sponsor: BRINKS HOFER GILSON & LIONE® Intellectual Property Law Worldwide

Cocktail Sponsored by: LOEB & LOEB LLP

Register Now • 888-224-2480 • AmericanConference.com/ParagraphIVSNF

AMERICAN CONFERENCE INSTITUTE

ACI's Hatch-Waxman Series

For the last decade, **ACI** has been at the forefront of bringing legal counsel and business executives for both brand name and generic pharmaceutical companies the finest programs to address the industry's most pressing Hatch-Waxman challenges. **ACI's** Hatch-Waxman series provides thoughtful analysis and practical solutions which will help you decipher the complexities of life cycle management, comprehend related policy considerations, and devise strategies and perfect trial advocacy skills for Paragraph IV litigation.

ACI's Hatch-Waxman Series Advisory Board

Stephen R. Auten
Vice President, IP
Sandoz, Inc. (Princeton, NJ)

Matthew P. Blischak
Vice President, Intellectual Property & Associate General Counsel
Sunovion Pharmaceuticals Inc. (Marlborough, MA)

Guy Donatiello
Vice President, Intellectual Property
Endo Pharmaceuticals (Chadds Ford, PA)

Lisa A. Jakob
Legal Director, IP Litigation
Merck & Company (Rahway, NJ)

George W. Johnston
Vice President & Chief Patent Counsel
Hoffman-La Roche (Nutley, NJ)

James P. Leeds
Assistant General Patent Counsel
Eli Lilly & Company (Indianapolis, IN)

Meg Snowden
VP, Intellectual Property
Impax Laboratories (Hayward, CA)

Shashank Upadhye
Vice President- Global Intellectual Property
Apotex, Inc. (Toronto, ON)

Timothy X. Witkowski, M.S., J.D.
Executive Director & Executive Counsel, Intellectual Property
Boehringer Ingelheim (Ridgefield, CT)

Distinguished Faculty:

Anders T. Aannestad
Partner
Morrison & Foerster LLP (San Diego, CA)

Aaron F. Barkoff, Ph.D.
Partner
McAndrews, Held & Malloy, Ltd. (Chicago, IL)

John Bauer
Partner
Fulbright & Jaworski L.L.P. (New York, NY)

Nicholas M. Boivin
Director, Intellectual Property Counsel
Cubist Pharmaceuticals, Inc. (Lexington, MA)

Richard de Bodo
Partner, Co-Chair Patent Litigation Practice
DLA Piper (Los Angeles, CA)

Barbara A. Fiacco
Partner
Foley Hoag LLP (Boston, MA)

The Honorable Jeremy Fogel (Invited)
Director, Federal Judicial Center
Former United States District Court Judge, Northern District of California (San Jose, CA)

Katherine I. Funk
Partner
Baker & McKenzie LLP (Washington, DC)

Ralph J. Gabric
Chair, Patent Litigation Practice
Brinks Hofer Gilson & Lione (Chicago, IL)

Amy E. Hamilton
Vice-President- Deputy General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

J. Elin Hartrum
Director, Intellectual Property
Gilead Sciences, Inc. (Foster City, CA)

Richard Horwitz
Partner
Potter Anderson & Corroon LLP (Wilmington, DE)

Irene E. Hudson
Principal
Fish & Richardson P.C. (New York, NY)

Mark T. Jansen
Partner, Kilpatrick Townsend & Stockton LLP
(San Francisco, CA)

Madison Jellins
Partner
Alston & Bird LLP (Palo Alto, CA)

Steffen N. Johnson
Counsel of Record
Winston & Strawn (Washington, DC)

Christopher J. Kelly
Partner
Mayer Brown LLP (Palo Alto, CA)

Alison Kessler
Head, US Patent Business Development & Strategic Licensing, Sandoz Inc. (Princeton, NJ)

T. O. Kong
Of Counsel
Wilson Sonsini Goodrich & Rosati
(San Francisco, CA)

Steven J. Lee
Partner
Kenyon & Kenyon (New York, NY)

Honorable Eugene F. Lynch
Mediator and Arbitrator, JAMS
Former United States District Court Judge, Northern District of California (San Francisco, CA)

David A. Manszpeizer
Partner
Wilmer Cutler Pickering Hale and Dorr LLP
(New York, NY)

Brian P. Murphy
Partner, Edwards Angell Palmer and Dodge LLP
(New York, NY)

Joseph O'Malley
Global Chair of Intellectual Property and Partner
Paul Hastings Janofsky & Walker LLP
(New York, NY)

Jeffry M. Nichols
Patent Attorney
Brinks Hofer Gilson & Lione (Chicago, IL)

Susan M. Perkins
Senior Director, Intellectual Property
Avila Therapeutics, Inc. (Waltham, MA)

Mark A. Perry
Partner
Gibson Dunn & Crutcher LLP (Washington, DC)

Dale L. Rieger, Ph.D., J.D.
Partner
Jones Day (San Diego, CA)

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

Michael D. Shumsky
Partner
Kirkland & Ellis LLP (Washington, DC)

Len S. Smith
Principal Intellectual Property Counsel
Medicis Pharmaceutical Corporation
(Scottsdale, AZ)

Meg Snowden
VP, Intellectual Property
Impax Laboratories, Inc. (Hayward, CA)

Mark E. Waddell
Partner
Loeb & Loeb LLP (New York, NY)

Peter D. Weinstein, Ph.D.
Corporate Counsel, IP
Baxter Healthcare Corporation
(Westlake Village, CA)

Warren Woessner
Founding Shareholder
Schwegman Lundberg & Woessner
(Minneapolis, MN)

Jessica Wolff
Partner
Cooley LLP (San Diego, CA)

Donald Zuhn
Partner
McDonnell Boehnen Hulbert & Berghoff LLP
(Chicago, IL)

The **must-attend** event for litigators from **brand name** and **generic companies** to share **insights** into increasingly high-stakes and complicated **Hatch-Waxman litigation**

With hundreds of billions of dollars at stake as blockbuster drugs go off patent in 2014, Hatch-Waxman litigation will only intensify as branded companies fight to delay generic entry and extend patent life through all means possible, and as generic companies fight amongst themselves for fewer opportunities to attain the prized 180-day exclusivity period. Constantly evolving case law including *Therasense*, *Caraco v. Novo-Nordisk*, and *Plavix* and legislative developments including long-awaited patent reform create more questions and will spawn more litigation as well.

At **American Conference Institute's** 2nd Annual West Coast edition of its acclaimed **Paragraph IV Disputes** conference, an experienced faculty of **renowned litigators** and **judges** will guide you through every stage of a Paragraph IV challenge to help you formulate the offensive moves and defensive plays for the next round in the no-holds barred fight for pharmaceutical product market share. Additionally, in the wake of major developments in pay-for-delay, learn what the **Federal Trade Commission** deems foul and fair in the settlement of Paragraph IV disputes in order to draft and structure a settlement that will receive FTC approval.

At this in-depth strategy session on the nuances of PIV litigation, our West Coast delegates will gain the tools to advance a novel claim or defense to protect patents and market share based on the expertise of trial leading patent counsel from generic and branded companies – and the judges – who have experienced the intricacies of Hatch Waxman litigation first hand. Featuring an up-to-the-minute analysis of the latest game-changing case law developments regarding inequitable conduct, inducement of infringement and the standard of invalidity, this conference will give our attendees the tools and litigation strategies to help both brand name and generic companies protect market share and ultimately profits.

In this costly and ruthless endgame, not a moment can be lost. Don't delay- register now by calling **1-888-224-2480**, faxing your registration form to **877-927-1563**, or logging onto to **www.AmericanConference.com/ParagraphIVSNF**.

CONTINUING LEGAL EDUCATION CREDITS

CLE Credits

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board in the amount of 10.5 hours (1.0 hours of ethics). An additional 4.5 credit hours will apply to participation in Boot Camp A and 2.0 hours for participation in Master Class B.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California in the amount of 9.0 hours (1.0 hours of ethics). An additional 4.0 credit hours will apply to participation in Boot Camp A and 2.0 hours for participation in Master Class B.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and **ACI** will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

Media Partners:

www.PharmCast.com Pharmaceutical Internet | patentbaristas.com | CanBiotech R&D Outsourcing Capital Sourcing Competitive Intelligence | pharmaphorum bringing healthcare together | Orange Book Blog | PharmaVOICE | Patent Docs Biotech & Pharma Patent Law & News Blog | Patently

GLOBAL SPONSORSHIP OPPORTUNITIES

With more than 500 conferences in the United States, Europe, Asia Pacific, and Latin America, **American Conference Institute** (**ACI**) provides a diverse portfolio devoted to providing business intelligence to senior decision makers who need to respond to challenges spanning various industries in the US and around the world.

As a member of our sponsorship faculty, your organization will be deemed as a partner. We will work closely with your organization to create the perfect business development solution catered exclusively to the needs of your practice group, business line or corporation.

For more information about this program or our global portfolio of events, please contact:

Wendy Tyler
Head of Sales, American Conference Institute
Tel: 212-352-3220 x5242 | Fax: 212-220-4281
w.tyler@AmericanConference.com

WHO YOU WILL MEET:

- Patent attorneys and litigators (in-house and law firm) who represent:
  - Brand name pharmaceutical companies
  - Generic pharmaceutical companies
  - Biopharmaceutical companies

Pre-Conference Boot Camp • Monday, December 5, 2011

1:00 p.m. – 5:00 p.m. *(Registration opens at 12:00 p.m.)*

Biosimilars Through the Hatch-Waxman Lens: Anticipating Litigation Challenges and Understanding the Evolving Landscape

Barbara A. Fiacco
Partner
Foley Hoag LLP (Boston, MA)

Steven J. Lee
Partner
Kenyon & Kenyon (New York, NY)

David A. Manszpeizer
Partner
Wilmer Cutler Pickering Hale and Dorr LLP (New York, NY)

In this highly in-depth session, an experienced faculty of Hatch-Waxman litigators will give you the tools necessary to position yourself strategically in the quickly evolving battle for biosimilars market share and will prepare you for the attacks on IP sure to come. While the patent resolution process under the biosimilars framework is still being fleshed out, our expert faculty of counsel to generic and branded companies will help you anticipate the future by drawing parallels to twenty five years Hatch-Waxman litigation and help you devise an immediate action plan for your biosimilars litigation strategies, factoring in potential regulatory hurdles and development costs.

Brace for the flood of litigation anticipated in the wake of this groundbreaking litigation:

- Steering clear of the gaps in the legislation: Analyzing the complex patent resolution mechanisms outlined in the statute and proactively preparing for the patent exchange process
- Planning for exchange requirements in the absence of an Orange Book equivalent
- Delineating the parameters of what will be considered infringement
- Determining which patents to strategically assert and at what phase
- Preparing for confidentiality issues inherent to turning over your dossier
- Remedies with respect to infringement, including when preliminary injunctions are available
- Evaluating trade secrets versus patent protection

Day One • Tuesday, December 6, 2011

7:15 **Registration and Continental Breakfast**

8:00 **Co-Chairs' Opening Remarks**

Madison Jellins
Partner
Alston & Bird LLP (Palo Alto, CA)

Mark E. Waddell
Partner
Loeb & Loeb LLP (New York, NY)

8:15 **Pre-Suit Due Diligence Strategies: The Branded Perspective on Proactively Anticipating Paragraph IV Challenges**

Nicholas M. Boivin
Director, Intellectual Property Counsel
Cubist Pharmaceuticals, Inc. (Lexington, MA)

J. Elin Hartrum
Director, Intellectual Property
Gilead Sciences, Inc. (Foster City, CA)

Susan M. Perkins
Director, Intellectual Property
Avila Therapeutics, Inc. (Waltham, MA)

Dale L. Rieger, Ph.D., J.D.
Partner
Jones Day (San Diego, CA)

- Evaluating the strength of the patents in your current pharmaceutical product portfolio
- Understanding the role of the Orange Book in patent strategy for branded and generic companies under Hatch-Waxman provisions
  - Listing patents in the Orange Book
  - What types of patents cannot be listed?
  - When and how are patents added to the Orange Book?
  - Factoring Orange Book use codes into your strategy
- Discerning when and how an ANDA applicant can challenge Orange Book listed patents and gauging when to reasonably expect a paragraph IV filing by a generic competitor
- Examining the different types of data exclusivities available through the FDA and how each relates to the timing of a Paragraph IV challenge
  - NCE
  - New use or indication
  - New formulation
  - Orphan drug
  - Pediatric
- Preparing for litigation
  - Preparing for discovery
  - Implementing of document retention policy
  - Putting a litigation hold put on all documents which may be discoverable
  - E-discovery
- Responding to a Paragraph IV challenge
  - Entering an authorized generics agreement
  - Claiming the label and REMS considerations
  - Filing a citizen's petition
- Reviewing the record for consistency between statements to the FDA and PTO

9:15 **Certifying Under Paragraph IV: Identifying the ANDA Applicant's Pre-Suit Considerations and Obligations**

Alison Kessler
Head, US Patent Business Development & Strategic Licensing
Sandoz Inc. (Princeton, NJ)

Anders T. Aannestad
Partner
Morrison & Foerster LLP (San Diego, CA)

- Deciding which patents to challenge
  - Compounds
  - Formulations
  - Process
  - Methods of use
- Factoring forfeiture into your Orange Book strategy
- Rethinking non-Orange Book patents
  - Innovator / non-innovator
  - New considerations/strategies for biological products vis- a-vis biosimilars legislation

- Getting a legal opinion on invalidity and non-infringement
  - Assessing when opinions are needed
  - Opinion of in-house v. outside counsel
- Pinpointing the best art and readying your argument
- Attempting to influence where and when the suit will occur
- Determining the contents of the Paragraph IV certification
- Filing the ANDA
  - Fulfilling requirements for FDA approval:
    - Pharmaceutically equivalent
    - Bioequivalent
  - Identifying triggers which may necessitate new bioequivalence studies

10:15 **Morning Coffee Break**

10:30 **Let the Games Begin: The Start of the Paragraph IV Law Suit – Pleadings and Considerations**

Aaron F. Barkoff, Ph.D.
Partner
McAndrews, Held & Malloy, Ltd. (Chicago, IL)

Richard Horwitz
Partner
Potter Anderson & Corroon LLP (Wilmington, DE)

Irene E. Hudson
Principal
Fish & Richardson P.C. (New York, NY)

Initial considerations

- Where should suit be filed?
  - Attempts by the generic to influence where and when the suit will occur
- Handicapping of judges and jurisdictions
- Surveying local patent rules
  - Knowing which district rules favor patent holders and patent challengers
    - New Jersey
    - Delaware
    - N.D. California
    - E.D. Texas
- Question of jury trial: exploring circumstances that may put you in front of a jury

Crafting the initial pleadings

- The complaint
  - Challenging the paragraph IV certification: alleging the patent is valid and infringed
    - What claims are made in the ANDA?
  - Avoiding Rule 11 sanctions
  - Assessing whether attorney's fees can be properly sought?
- The answer and counterclaims
  - De-listing improperly listed patents
  - Antitrust and unfair competition claims
  - Assertions of inequitable conduct post-*Therasense*
    - The generic point of view on attorneys' fees and Rule 11

Declaratory Judgments

- Understanding the MMA declaratory judgment provisions and the CAFC's interpretation of these provisions
  - Two prong test
- When is it appropriate to move for a DJ
- Circumstances when a DJ will be granted?
- Should DJ be sought on all patents – listed and not listed?

Factoring in the 30-month stay

- Understanding the scope and limits of the 30-month stay under the MMA
- Options and strategies for the patent holder if the stay expires during the course of litigation
- Early termination of the stay

11:30 **New Standards and Controversies in Double Patenting Type Obviousness: Repercussions for Paragraph IV Challenges**

Amy E. Hamilton
Vice-President- Deputy General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

John Bauer
Partner
Fulbright & Jaworski L.L.P. (New York, NY)

Joseph O'Malley
Global Chair of Intellectual Property and Partner
Paul Hastings Janofsky & Walker LLP (New York, NY)

- Analyzing the evolving state of the law on double patenting type obviousness and its impact on Paragraph IV litigation strategies
- How has *Sun Pharm. Indus. v. Eli Lilly & Co.* changed the double patenting standard?
  - Deciphering the Federal Circuit's rationale regarding an extension of a prior art analysis to a double patenting controversy
  - Exploring why the Federal Circuit strayed from its prior precedent holding that double-patenting is based upon that which is already claimed
  - Dissecting the importance of the dissent in this opinion
    - Comparing obviousness based on prior art to obvious-type double patenting
    - Examining the heretofore used "obvious variant" standard
  - Assessing the likelihood of whether this case will go up to the Supreme Court
- *Boehringer Ingleheim Int'l, et al. v. Barr Labs, Inc*
  - When does seeking patent term extension give rise to an allegation of double patenting?
  - Under which circumstances will a court allow for the filing of a terminal disclaimer to avoid double patenting controversy?
- Brand –name and generic strategies for navigating the new double patenting landscape
- Examining the link between double patenting and inequitable conduct

12:30 **Afternoon Refreshment Break**

2:00 **No Holds Barred: Fighting for or Defending Against the Coveted 180 Day Exclusivity Stay**

Madison Jellins
Partner
Alston & Bird LLP (Palo Alto, CA)

Michael D. Shumsky
Partner
Kirkland & Ellis LLP (Washington, DC)

Jessica Wolff
Partner
Cooley LLP (San Diego, CA)

- Understanding how forfeiture of 180-day exclusivity has become the impetus for generic/generic litigation
  - Protecting market share or something more?
- How have authorized generics changed the playing field relative to 180-day exclusivity?
- Strategies employed in and leading to these law suits
  - Citizens petitions to block other generic competitors
- How to better position your company in these challenges
- Predicting future trends in this type of litigation
- Forfeiture provisions: circumstances under which exclusivity is forfeited
  - When can forfeiture of another's exclusivity occur?
  - How do subsequent P IV filers influence forfeiture?
- Deciphering the FDA's stance on pre and post –MMA 180-day exclusivity
- Interpreting the "earlier of", later of" language in making a forfeiture determination
- Triggering "the failure to market" provision
- Evaluating the impact of "delisting" on forfeiture
- Forfeiture relative to patent expiration
- When can the 180-day exclusivity period be transferred to another ANDA applicant?
- Evaluating when the 180-day exclusivity period can be relinquished, and exploring the consequences
  - Understanding the relevance to the outcome of a Paragraph IV case
- When can a brand "park" a generic's exclusivity?
- Defining "shared exclusivity"
- Exploring regulatory bars to exclusivity
- Understanding the role of Citizen's Petitions in Hatch-Waxman litigation
  - When should they be filed and how to avoid their being viewed as a delaying tactic
  - How generics are using citizens petitions to block other generic competitors

3:15 **Afternoon Refreshment Break**

3:30 **A View from the Bench on Paragraph IV Litigation**

The Honorable Jeremy Fogel (Invited)
Director, **Federal Judicial Center**
Former United States District Court Judge, Northern District of California (San Jose, CA)

Honorable Eugene F. Lynch (Retired)
Mediator and Arbitrator, **JAMS**
Former United States District Court Judge, Northern District of California (San Francisco, CA)

Moderator

Richard de Bodo
Partner, Co-Chair Patent Litigation Practice
DLA Piper (Los Angeles, CA)

Formulate your Paragraph IV litigation strategies based upon the insights of renowned jurists fluent in the nuances of Paragraph IV litigation. Experienced judges who have handled some of the most active Paragraph IV dockets in the country will share their thought and insights on some of the most pressing issues facing both patent holders and patent challengers. Come prepared with your most pressing questions and learn practice pointers to hone your strategies in Court.

5:00 **Conference Adjourns to Day Two**
Cocktail Reception for all Attendees & Speakers

Hosted by LOEB & LOEB LLP

Day Two • Wednesday, December 7, 2011

7:30 **Continental Breakfast**

8:15 **Co-Chairs' Opening Remarks**

8:30 **Carve Outs and Inducement Controversies: Examining the Intersection Between a Drug's Patent and Its Label**

Meg Snowden
VP, Intellectual Property
Impax Laboratories, Inc. (Hayward, CA)

Steffen N. Johnson
Counsel of Record
Winston & Strawn (Washington, DC)

Jeffry M. Nichols
Patent Attorney
Brinks Hofer Gilson & Lione (Chicago, IL)

Mark A. Perry
Partner
Gibson Dunn & Crutcher LLP (Washington, DC)

- Comprehending the newfound significance of inducement actions post the Supreme Court's decision in *Global Tech v. SEB*
  - When does a label encourage others to infringe?
  - Mens rea requirements – what constitutes willful blindness?
  - Indirect vs. direct infringement
- *AstraZeneca LP v. Apotex, Inc.*: the role of Section 8 carve-outs and the inducement controversy
- *Caraco Pharmaceutical v. Novo Nordisk A/S*
  - When can a generic company bring an action to correct an overbroad method of use description?
  - What is an unreasonable expansion of a use code?
- Skinny labeling challenges: is there a way around patents?

9:45 **The Post-*Therasense* World: Pleading and Defending Against Inequitable Conduct Allegations Under the Heightened Standard for Materiality and Intent**

Ralph J. Gabric
Chair, Patent Litigation Practice
Brinks Hofer Gilson & Lione (Chicago, IL)

Peter D. Weinstein, Ph.D.
Corporate Counsel, IP
Baxter Healthcare Corporation (Westlake Village, CA)

Warren D. Woessner, Ph.D.
Founding Shareholder
Schwegman Lundberg & Woessner (Minneapolis, MN)

Donald Zuhn
Partner
McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

Ethics Credits

Once dubbed the "plague" of patent claims by the Federal Circuit, the defense of inequitable conduct was often pled and caused practitioners to submit reams of prior art to the PTO. After the Federal Circuit's decision in *Therasense*, the inequitable conduct defense has become much more difficult to prove. In this session, leading practitioners examine the practical effect of *Therasense* and what the future of inequitable conduct will be now that Rule 56 has been discarded, the "sliding scale" is gone, and the bar has been raised for both prongs of the test for inequitable conduct:

- Is the defense of inequitable conduct dead or merely wounded?
- Working within the heightened standards for materiality and intent set by the Court in Therasense- Exploring the new "but-for" test for materiality
  - Exploring the "but-for" test for materiality: what comes next?
  - Meeting the "deliberately planned and carefully executed" exception
  - Showing the threshold level of intent
  - Determining standards for fraud and unclean hands
- Meeting the requirements for disclosure to PTO during prosecution
  - Disclosing related prosecution and applications in the US and abroad
  - Disclosing foreign language documents
  - When is a document cumulative?
  - When is disclosure excessive– burying prior art?
  - The new PTO materiality rules
- The proper role of inequitable conduct in litigation— How to drop the "atomic bomb" of patent law

10:45 **Morning Coffee Break**

11:00 **Damages and Injunctions: Exploring the Consequences and Conundrums of Launching at Risk**

Mark T. Jansen
Partner
Kilpatrick Townsend & Stockton LLP (San Francisco, CA)

T. O. Kong
Of Counsel
Wilson Sonsini Goodrich & Rosati (San Francisco, CA)

Brian P. Murphy
Partner
Edwards Angell Palmer and Dodge LLP (New York, NY)

Len S. Smith
Principal Intellectual Property Counsel
Medicis Pharmaceutical Corporation (Scottsdale, AZ)

- Weighing the risks and benefits of launching at risk during litigation or the appeal period
- Seeking a preliminary injunction in the event that the stay ends in the course of the litigation
  - Posting of bond by the branded side
- Exploring the possibility of a stipulated injunction
  - Why a stipulated injunction may be of benefit to both sides
- Appealing to the CAFC
- *Sanofi v. Apotex (Plavix)*: why is this case involving stipulated damages causing new concerns for damages for launching at risk?
- How are damages quantified?
  - Brand-name vs. generic point of view
- Lost profits:
  - How much can be factually assessed?
  - Looking at sales
  - When is profit a true measure of damages in these cases?
    - How to assess whether the drug is truly profitable?
  - When is it the only thing that you can seek?
- Reasonable royalties:
  - Basis for royalty
  - Looking at market share
  - Assessing value of a hypothetical license
  - Tracing this calculation back to the point where infringement began
- Under which circumstances can damages be mitigated?

12:30 **Conference Adjourns**

Post-Conference Master Class
Wednesday, December 7, 2011

2:00 p.m. – 5:00 p.m. *(Registration opens at 1:30 p.m.)*

SETTLING PARAGRAPH IV DISPUTES: Drafting and Negotiating Strategies for Brand-Name and Generic Companies – A Hands-On, Practical Approach

With insight from the Federal Trade Commission and from leading antitrust lawyers, this hands-on, interactive session will examine how in the current environment, parties to a Paragraph IV dispute can resolve their differences and receive the government's blessing. The Federal Trade Commission and state attorneys general, now with the DOJ's support, have challenged a number of patent dispute settlements on antitrust grounds. "Reverse settlement" or "pay-for-delay" agreements have been viewed by the FTC as a very anticompetitive practice. Both brand names and generic drug companies have expressed their frustration in attempting to come to an agreeable resolution in this matter.

2:00 **FTC Keynote: Pay For Delay Settlements**

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

In this session, Commissioner Rosch will discuss the FTC's position on these agreements and address such matters as:

- The enforcement of the MMA reporting requirements
- FTC and DOJ alignment on "pay-for-delay" agreements
- The status of pending legislation regarding these settlements
- The competitive implications of other pharmaceutical life cycle management strategies
- The findings of the FTC's authorized generic's study

3:00 **Obtaining Optimal Terms and Minimizing Antitrust Concerns When Settling Paragraph IV Disputes**

Katherine I. Funk
Partner
Baker & McKenzie LLP (Washington, DC)

Christopher J. Kelly
Partner
Mayer Brown LLP (Palo Alto, CA)

The leaders will explore best practices to reach settlements that the parties and the FTC can live with. The session will help you:

- Draft and structure an agreement that will minimize FTC concerns
- Identify and avoid red flags that may lead to FTC scrutiny
- Anticipate possible requirements under proposed legislation
- Understand the role of authorized generics in these agreements and the FTC's view on this topic
- Incorporate elements that emphasize the competitive nature of the agreement
- Devise strategies to employ pending completion of the FTC's review

American Conference Institute's *2nd West Coast Edition*

ACI's HATCH-WAXMAN SERIES

Paragraph IV Disputes

Expert Insights on Hatch-Waxman Litigation Strategies for Brand Names and Generics

December 6 – 7, 2011 • Hotel Nikko • San Francisco, CA

PLUS, don't miss the in-depth and interactive sessions that will give you the litigation expertise to truly set yourself apart from the competition:

Pre-Conference Boot Camp:
Biosimilars Through the Hatch-Waxman Lens: Anticipating Litigation Challenges and Understanding the Evolving Landscape

Post-Conference Master Class:
SETTLING PARAGRAPH IV DISPUTES featuring an **FTC Keynote on Pay-for-Delay Settlements**

REGISTRATION FORM

PRIORITY SERVICE CODE

866L12.WEB

ATTENTION MAILROOM: If undeliverable to addressee, please forward to:
Patent Counsel, IP Counsel, Patent Litigator

Can be recycled

CONFERENCE CODE: 866L12-SNF

☐ **YES! Please register the following delegate for Paragraph IV Disputes**

CONTACT DETAILS

NAME _____ POSITION _____

APPROVING MANAGER _____ POSITION _____

ORGANIZATION _____

ADDRESS _____

CITY _____ STATE _____ ZIP CODE _____

TELEPHONE _____ FAX _____

EMAIL _____ TYPE OF BUSINESS _____

☐ I would like to receive CLE accreditation for the following states: _____. See CLE details inside.

FEE PER DELEGATE	Register & Pay by Oct. 12, 2011	Register & Pay by Nov. 4, 2011	Register after Nov. 4, 2011
☐ ELITEPASS*: Conference & Both Boot Camp & Master Class	$3195	$3295	$3495
☐ Conference & Boot Camp	$2595	$2695	$2895
☐ Conference & Master Class	$2595	$2695	$2895
☐ Conference Only	$1995	$2095	$2295

☐ I cannot attend but would like information on accessing the ACI publication library and archive

**ELITEPASS is recommended for maximum learning and networking value.*

PAYMENT

Please charge my ☐ VISA ☐ MasterCard ☐ AMEX ☐ Please invoice me

NUMBER _____ EXP. DATE _____

CARDHOLDER _____

☐ I have enclosed my check for $_____ made payable to **American Conference Institute** (T.I.N.—98-0116207)

☐ ACH Payment ($USD)
Please quote the name of the attendee(s) and the event code 866L12 as a reference.
For US registrants:
Bank Name: HSBC USA
Address: 800 6th Avenue, New York, NY 10001
Account Name: American Conference Institute
UPIC Routing and Transit Number: 021-05205-3
UPIC Account Number: 74952405
Non–US residents please contact Customer Service for Wire Payment information

Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI** reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **ACI** for changes in program date, content, speakers, or venue.

Hotel Information

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI – Paragraph IV" conference to receive this rate:

Venue: Hotel Nikko San Francisco
Address: 222 Mason Street, San Francisco, California 94102, USA
Reservations: 415–394–1111 / 800–248–3308

Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1–877–927–1563, or email data@AmericanConference.com.

5 Easy Ways to Register

MAIL American Conference Institute
45 West 25th Street, 11th Floor
New York, NY 10010

PHONE 888–224–2480

FAX 877–927–1563

ONLINE
AmericanConference.com/ParagraphIVSNF

EMAIL
CustomerService
@AmericanConference.com

CONFERENCE PUBLICATIONS

To reserve your copy or to receive a catalog of **ACI** titles go to www.aciresources.com or call 1–888–224–2480.

SPECIAL DISCOUNT

We offer special pricing for groups and government employees. Please email or call for details.
Promotional discounts may not be combined. **ACI** offers financial scholarships for government employees, judges, law students, non–profit entities and others. For more information, please email or call customer service.